(358)

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/04

A1

(11) International Publication Number: **WO 98/38922**

(43) International Publication Date: 11 September 1998 (11.09.98)

(21) International Application Number: PCT/US98/04387

(22) International Filing Date: 5 March 1998 (05.03.98)

(30) Priority Data:
08/814,740 7 March 1997 (07.03.97) US

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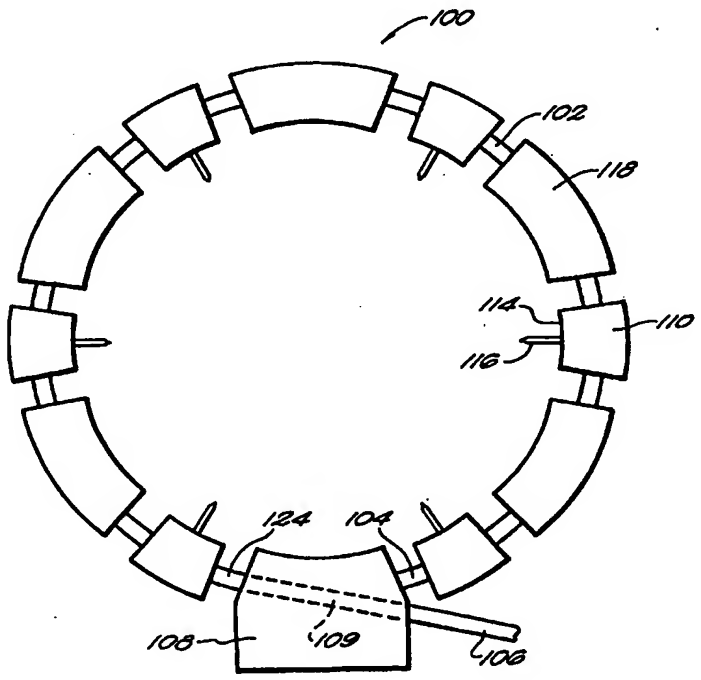
(81) Designated States: European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: EXOVASCULAR ANASTOMOTIC DEVICE

(57) Abstract

An anastomotic device (100) includes a flexible member (102), formable into a loop and a plurality of tissue penetrating anchoring elements (110) slide mounted on the flexible member. The tissue penetrating anchoring elements (116) extend generally towards a center of the loop formed by the flexible member. The device is adapted for anastomosing vessel segments or a vessel and a graft. In a further embodiment, an exo–vascular anastomotic device is suitable for end to side anastomoses, and it includes an anastomotic ring and a harness assembly.



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EXOVASCULAR ANASTOMOTIC DEVICE

FIELD OF THE INVENTION

The present invention relates to devices useful with surgical anastomoses and more particularly to a sutureless anastomotic device.

BACKGROUND OF THE INVENTION

The joining of one hollow or tubular organ to another in a patient, known as anastomosis, is a common surgical procedure. Blood vessels serve as an example of such organs for which anastomoses may be required. For example, a sharp foreign object or severe trauma can sever a blood vessel, requiring an anastomotic procedure to restore patency of the vessel. If a vessel is occluded or otherwise diseased, a bypass procedure may include replacing the occluded section with a portion of a vessel from another part of the body. Also, if a portion of a vessel is diseased or damaged, a synthetic graft, or prosthesis, may be introduced to replace that portion of the vessel.

Anastomoses procedures have been traditionally effected by using sutures to join the vessels and/or grafts. It will be appreciated by one of ordinary skill in the art that there are significant disadvantages associated with suturing vessels. For example, a high level of skill is required to properly join the vessels and/or grafts. The suturing of vessels and/or grafts is, moreover, a procedure that is quite time consuming. To anastomose a blood vessel having a diameter in the range of about five to twenty-five millimeters, approximately twenty to thirty well placed stitches must be placed about the circumference of the vessel, requiring at least fifteen minutes under optimal conditions.

The suturing process is further complicated by friable and rigid, calcified vessels increasing the time required for the procedure. As is known to one of ordinary skill in the art, longer operative times are associated with a greater likelihood of heart attack and infection. Moreover, any improper suturing can result in serious medical consequences, including hemorrhaging and infection.

Anastomosis of living vessels requires the vessel layers to be positioned properly with respect to each other. As shown in FIG. 1, a vessel, such as a human

artery 10 has an inner layer (intima) 12, a middle layer (media) 14, and an outer layer (adventitia) 16. To anastomose a vessel or graft, the sutures must be precisely placed using a curved needle to pierce the vessel first from the outside, and then from the inside back to the outside of the vessel. As noted above, such a suturing process is time consuming and demands a high level of precision. Time is especially critical in procedures that require repair of a major artery.

Suture-based anastomoses have inherent limitations because the mechanical strength of the sutures join the graft and the vessel. Suturing can be especially difficult in cases where a vessel is so diseased or so severely damaged that there is only a limited amount of healthy tissue to which the sutures can be anchored. The brittleness of some diseased vessels can render them less amenable to suture-based anastomotic procedures.

There are inherent advantages to minimally invasive laparoscopic procedures. However, the limited degree of freedom afforded by the closed surgical environment compounds the difficulties associated with suture-based anastomotic procedures.

Because suture-based anastomotic procedures suffer from the drawbacks noted above, attempts have been made to develop sutureless anastomotic devices. See, for example, U.S. Patents Nos. 4,470,415, 4,917,087, 4,930,674, and 5,486,187. However, the complexity of such devices and/or their lack of ease of use have limited their clinical acceptance. There is thus a need for a sutureless anastomotic device that can be easily and effectively used in a variety of anastomotic procedures.

SUMMARY OF THE INVENTION

The present invention provides a sutureless anastomotic device useful in sutureless anastomotic procedures. In one embodiment the anastomotic device is an exovascular anastomotic device. Although the invention is primarily described and illustrated as an exovascular anastomotic device, it is understood that it can be used for other anastomoses procedures such as gastro-intestinal anastomoses.

The device, in its initial configuration, is an elongate flexible member having first and second ends. One or more anchoring elements are disposed on the flexible

member. The anchoring elements preferably are each in the form of a tubular body having an axial passageway formed therein. One surface of the anchoring element has formed thereon at least one tissue-penetrating projection. The anchoring elements are preferably slidably mounted, through the axial passageway, upon the flexible member. Optimally, one or more spacer elements may be disposed on the flexible member between each, or selected, adjacent anchoring members to control the positioning of the anchoring members.

The flexible member is formable into a loop of an adjustable diameter. In one embodiment, one of the first or second ends of the flexible member includes a locking mechanism having an opening formed therein. In operation, the other of the first or second ends of the flexible member is threaded through the opening of the locking mechanism so that the flexible member assumes the shape of a loop. In this loop configuration, the anchoring elements are circumferentially oriented with the tissue-penetrating projections being inwardly directed, either radially inward or at a selected angle to the radius. Preferably, the anchoring elements are slidably mounted on the loop so that before installation of the device in an anastomotic procedure they can be positioned as needed; once the device is initially placed on a vessel the anchoring elements are stationary.

Surface features are preferably formed on at least one surface of the flexible member. These surface features interact with a complementary surface feature or other structure formed in the opening of the locking mechanism so that the end inserted into the locking mechanism can only be moved in one direction with respect to the locking mechanism. Preferably, this unidirectional movement enables the loop to be adjusted only in a manner to decrease its diameter.

In one embodiment, the anastomotic device is used by forming the flexible member into a loop that is circumscribed about an end of a first vessel segment. The end of the first vessel segment is then overlapped with an end of a second vessel segment. An initial adjustment to the diameter of the loop is made to cause the tissue-penetrating projections to penetrate the vessels. Thereafter, the flexible member is moved with respect to the anchoring elements (which remain stationary) to reduce the size of the loop until it is properly dimensioned about the vessels to

anastomose the first and second vessel segments. An intravascular obturator (such as an obturator balloon) may be positioned within the vessel to assist in the anastomotic procedure.

In another embodiment, the anastomotic device of the invention can be used for an end-to-side anastomosis. In this embodiment, the device includes an anastomotic ring and a harness assembly having a harness ring coupled to at least one locking band. The anastomotic ring optionally includes at least one filamentary member fixedly secured to the anastomotic ring.

An end-to-side anastomosis can be conducted by placing a vessel or graft within the harness ring and then the anastomotic ring, and everting an end of the vessel or graft segment over the anastomotic ring. A receiving vessel is cut to form a substantially round hole, the opening of which tapers inwardly from the adventitia to the intima. The everted end of the vessel or graft is placed into the complementary hole formed in the receiving vessel and the harness ring is urged toward the anastomotic ring by cinching the locking band to the receiving vessel. The harness ring retains the everted end of the graft and anastomotic ring in the hole in the receiving vessel. The filamentary member(s) can secure the anastomotic ring to the harness assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the following drawings, in which:

FIG. 1 is a prior art perspective view of an artery;

FIG. 2 is a side view of an exovascular anastomotic device in accordance with the present invention shown in an unengaged position;

FIG. 3 is a side view of the anastomotic device of FIG. 2 shown in an engaged position;

FIG. 4 is a side view of an anchoring element forming a portion of the anastomotic device of FIG. 2;

FIG. 5 is a enlarged sectional view of a portion of the locking mechanism and the flexible member, forming a portion of the anastomotic device of FIG. 2;

FIG. 6 is a sectional view of a spacer element forming a portion of the anastomotic device of FIG. 2;

FIG. 7 is a cross sectional view of the anastomotic device of FIG. 2 disposed on a vessel;

FIG. 7A is a perspective view of the anastomotic device of FIG. 7;

FIG. 7B is an enlarged cross sectional view of an alternative embodiment of the anastomotic device of FIG. 7;

FIG. 7C is a side view of a further embodiment of the anastomotic device of FIG.7;

FIG. 7D is a perspective sectional view of an obturator adapted for use in conjunction with the anastomotic device of FIG. 7;

FIG. 8 is a cross sectional view of an alternative embodiment of an anastomotic device in accordance with the present invention;

FIG. 9 is a cross sectional view of a further embodiment of an anastomotic device in accordance with the present invention;

FIG. 9A is a perspective view of a prior art vessel having a hole punched therein;

FIG. 9B is a cross sectional view of the vessel of FIG 9A;

FIG. 10 is a perspective view of an anastomotic ring forming a portion of the anastomotic device of FIG. 9; and

FIG. 11 is a top view of a harness assembly forming a portion of the anastomotic device of FIG. 9.

DETAILED DESCRIPTION OF THE INVENTION

The drawings are understood to be illustrative of the concepts disclosed herein to facilitate comprehension of the invention. Further, the drawings are not to scale, and the scope of the invention is not to be limited to the particular embodiments shown and described herein.

Referring to FIGS. 2-8, a sutureless anastomotic device 100 includes a flexible member 102 having a first end 104 and a second end 106. A locking mechanism 108, or similar device, enables the formation of a closable loop and is

secured to the first end 104 of the flexible member 102. The second end 106 is threaded through an opening 109 in the locking mechanism to form a loop. Anchoring elements 110 are slidably mounted on the flexible member 102. The anchoring elements 110 are preferably in the form of a tubular body 111 defining an axial passageway 112 therein. The anchoring elements 110 each include a first surface 114 having formed thereon a tissue-penetrating projection 116. In an exemplary embodiment, one or more spacer elements 118 can be disposed on the flexible member 102 between adjacent anchoring elements 110 to control the positioning and/or spacing of the anchoring elements.

It is understood that various alternative structures may be used as an alternative to locking mechanism 108. Suitable structures must allow the formation of a loop, having an adjustable diameter, from an initially elongate member. For example, the locking mechanism can include a screw element, advancement of which moves one end of the flexible member relative to the other end of the flexible member to reduce the diameter of the loop.

Each of the tissue-penetrating protrusions 116 include a first end 119 coupled to the tubular body, a generally pointed second end 120, and an intermediate portion 122. In an exemplary embodiment, the intermediate portion 122 has an annular cross section defining a substantially constant diameter along the length thereof. The tissue-penetrating protrusion 116 has a length in the range of about 0.1 to 5 millimeters, and preferably is about one millimeter. The diameter of protrusion 116 at the intermediate portion 122 is in the range of about 0.01 to 0.3 millimeters, and preferably about 0.1 millimeters. Other geometries for the tissue-penetrating protrusions 116 are also possible, such as conical and flattened, for example.

The anchoring elements 110 are formed from biocompatible materials having good mechanical properties. Exemplary materials include stainless steel, titanium, titanium alloys, metals, ceramics, and suitably rigid, biocompatible polymers. The device 100 is shown having six anchoring members 110, each having one tissue-penetrating protrusion 116. However, it is understood that a greater or lesser number of anchoring members 110 may be used, and that a member 110 may have more than one protrusion 116 (FIG. 7C). In a further

embodiment, the second end 120 of the protrusions includes one or more barbs 123 (FIG. 7B) for securing the protrusions in tissue. Further, the protrusions 116 can extend from the tubular body 111 at any point on the first surface 114.

In an exemplary embodiment, the anchoring elements 110 are freely movable with respect to the flexible member 102 before protrusions 116 are embedded in tissue. The flexible member 102 is of sufficient width so as to provide lateral stability for the tissue-penetrating protrusions 116. Generally, the width of flexible member 102 ranges from about 1.5 millimeters to 2 centimeters, and more preferably from about 3 to 4 millimeters. The tissue-penetrating protrusions 116 should generally be oriented to form an acute angle with respect to a radial center point of the loop (FIG. 7B). This angle is generally in the range of about five to eighty degrees, and more preferably is about thirty degrees. The optimal angle for the protrusions 116 is determined by the amount of deformation that occurs as the protrusions penetrate tissue. More specifically, the more rigid the protrusions 116, the more the protrusions can be angled with respect to the radial centerpoint of the loop. In another embodiment, the protrusions 116 are directed to the radial centerpoint of the loop formed by the flexible member.

As illustrated in Figures 2 and 5, the flexible member 102 defines a first surface 124 having a plurality of surface features 126, which in an exemplary embodiment are spaced teeth. The surface features 126 can be disposed on the first surface 124 or an opposing surface of the flexible member 102, i.e., inward or outward with respect to the loop. The opening 109 in the locking mechanism 108 may include a structure such as a surface feature in the form of an arm 127, or a similar member, that is engageable with a respective one or more of the teeth 126 associated with the flexible member 102. In a preferred embodiment, each of the teeth 126 includes a sloped surface 128 defining an acute angle with respect to the longitudinal axis X of the flexible member and an engagement surface 130 extending generally perpendicular to the longitudinal axis X. It will be appreciated by one of ordinary skill in the art that the size of the teeth 126 may vary substantially. In an exemplary embodiment, the sloped surface 128 is about 0.3 millimeters in length and the engagement surface 130 is about 0.1 millimeters in height. The arm 127 is

biased towards the flexible member 102 and contacts the engagement surface 130 of the respective tooth. As the flexible member 102 is moved in a first direction, indicated by arrow 132, the arm 127 elastically deforms as it slides up the sloped surface 128 and then returns to its original position as it reaches an adjacent engagement surface. The arm 127 operates in conjunction with the engagement surface 130 to prevent movement of the flexible member 102 in a direction opposite of the first direction 132. Thus, the surface features of the locking mechanism and the flexible member permit unidirectional movement of the flexible member with respect to the locking mechanism 108 to allow only a reduction in the size of the loop.

The flexible member 102 can be made from a variety of suitably flexible materials including biocompatible polymers. Exemplary materials include nylon polymers. The flexible member 102 can be formed from inelastic or moderately elastic materials known to one of ordinary skill in the art. Moderately elastic flexible members are useful as they expand in response to a pulse of a fluid through a vessel. In a further embodiment useful in gastro-intestinal applications, the device is formed from biodegradable polymers, such as polyglyconate, so that the device need not be surgically removed after healing has taken place. Commercially available examples of such materials include POLYSORB and MAXON.

As shown in Figure 6, the optional spacer elements 118 preferably are tubular in shape, defining an aperture 134 through which the flexible member 102 may pass. Each of the spacer elements 118 includes an outer surface 136 and an inner surface 138 (as configured on the loop), wherein the inner surface is about the same distance from the flexible member 102 as the surface 114 of the anchoring elements 114. In one embodiment, one or more spacer elements 118 are located between adjacent tissue-penetrating protrusions 116 so that the anchoring elements are generally equally spaced about the loop as the size of the loop is reduced. However, it is understood that the anchoring elements need not necessarily be equally spaced. The spacer elements 118 preferably have sufficient flexibility or other physical characteristics (e.g., geometry) to enable then to conform to the curvature of the loop.

The dimensions of the spacer element can vary depending upon the requirements of a given application. The thickness (or height) of the spacer elements should be consistent with the thickness of the tubular body portion of anchoring elements 114 to form a substantially continuous contact surface with a vessel or a graft. Typically, the thickness is in the range of about 0.02 to 0.2 millimeters. The width of the spacer elements 118 is in the range of about one to twenty millimeters, and preferably, is about the same width as the anchoring elements. The length of spacer elements 118 is in the range of about one half to about twice the length of the anchor elements, and it is understood that the spacer elements can be longitudinally compressible.

In one embodiment, the spacer elements can have a longitudinal slit along the length thereof so that one or more selected spacer elements can be removed or added to the flexible member 102. In addition, a series of spacer elements 118 of the same or differing lengths can be disposed between adjacent anchor elements 110 to provide a desired spacing of the anchoring elements (FIG. 7C). One or more selected spacer elements can be removed or added to adjust the minimum diameter of the loop. In another embodiment, the spacer elements are formed from a material that can be cut with relative ease so that one or more selected spacer elements can removed from the loop.

One of ordinary skill in the art will appreciate that the spacer elements can be made from a variety of biocompatible materials, including metals, polymers and ceramics. Polymeric materials are preferred for most applications, and suitable exemplary polymers include polytetrafluoroethylene (PTFE) and other polymers known to those of ordinary skill in the art.

Figures 7 and 7A illustrate the use of a sutureless anastomotic device 100 according to the present invention in a distal anastomosis of an end 150 of a native blood vessel 152 and an end 154 of a graft 156. As indicated by arrow 159, the blood flow is in the direction from the graft 156 to the vessel 152. To effect this procedure, the end 154 of the graft is moved toward the device 100 so that the device, in the form of a loop, surrounds the graft 156. The end 150 of the vessel 152 is inserted within the end 154 of the graft so that portions of the vessel and the

graft overlap at an overlap area 158. The flexible member 102 of the device is moved with respect to the locking mechanism (and the anchoring members) to decrease the size of the loop. As the loop contracts, the tissue-penetrating protrusions 116 penetrate the graft 156 and then the vessel 152. Contemporaneously, the spacer elements 118 slide with respect to the flexible member 102 so that surfaces 114,138 of the anchoring elements and the spacer elements attain circumscribed engagement with an exterior surface 160 of the graft. As noted above, the anchoring elements 110 are freely slidable upon the flexible member 102. Once protrusions 116 penetrate tissue, however, anchoring elements 110 are stationary with respect to flexible member 102.

Upon initial penetration of the surface of the graft 156, the tissue-penetrating protrusions 116 are urged radially inward by the flexible member 102, without circumferential movement, as the loop diameter is further decreased. If the protrusions 116 are angled with respect to a radial centerpoint of the loop, tangential and radial force vectors are applied to the protrusions as the loop size decreases. The spacer elements 118 and the anchor elements provide substantially continuous contact with and substantially constant pressure on the graft outer surface 160 to prevent gaps that could result in leakage of blood between the artery 152 and the graft 152. The device is of sufficient flexibility so as to conform to any irregularities in the outer surface of the vessel.

The diameter of the loop is decreased by moving the flexible member 102 with respect to the locking mechanism 108 and the anchoring elements. One of ordinary skill in the art will appreciate that a variety of suitable applicator devices can be used. In one example, a suitable applicator gun (not shown) includes a head portion, a manual actuator mechanism , and a handle. In operation, the head portion abuts the locking mechanism 108 and the actuator mechanism engages the surface features 124 of the flexible member 102 for longitudinally displacing the flexible member with respect to the locking mechanism. A user, such as a surgeon, activates the actuator mechanism to manipulate the loop to a desired size.

In another embodiment, shown in Figure 7C, the anastomotic device 100 can include one or more crimping elements 155 movably disposed on the flexible

member 102. Such crimping members can be useful to close any gap 161 formed between the device 100 and an external surface of a graft. The crimping element 155 includes a tubular body 157 and an arcuate projecting member 159 extending from the tubular body. The projecting member 159 substantially conforms to the arcuate shape of the graft, thereby eliminating any gap. In addition, where a graft is to be anastomosed to a vessel having a smaller diameter, any excess graft material can be gathered at an end 163 of the projecting member 159 and pressed against an adjacent spacer element 118 or anchor element 110 to eliminate spaces or wrinkles in the graft.

In one embodiment, illustrated in Figure 7, the tissue-penetrating protrusions 116 are of a length such that they do not extend into the lumen of the affected vessel. Instead, the tissue-penetrating protrusions 116 lodge in the healthy adventitia of the vessel, and do not affect any diseased intima having a layer of calcified plaque 162. A balloon or rigid obturator (e.g., 181 in FIG. 7D) can be inserted into the lumen of the vessel in a manner known to those of ordinary skill in the art to prevent collapse of the vessel as the device 100 is actuated. In one example, the obturator can be inserted by way of a catheter through the groin area.

As shown in FIG. 7D, a balloon obturator 181 can include an inner layer 183 and a sheath 185 surrounding the inner layer. The sheath 185 resists penetration by the tissue-penetrating protrusions 116 and protects the inner layer 183 from puncture as the anastomotic device anastomoses one vessel to another. The sheath 185 is formed from suitable puncture resistant materials, such as latex.

In another embodiment, shown in FIG. 8, a device 100' includes tissue-penetrating protrusions 116' having a length sufficient to penetrate the intima and extend into the lumen of a vessel and into contact with a rigid obturator 164. Such contact with obturator 164 causes the tissue-penetrating protrusions 116' to deform as the device fully engages the vessel. The resulting deformed tissue-penetrating protrusions 116' can help to maintain a seal between the graft 156 and vessel 152 to prevent or minimize any leakage of blood between the vessel and the graft. This embodiment is well suited for a distal anastomosis in which the graft overlaps the end of the vessel and blood flows from the graft to the vessel.

Figures 9-11 illustrate an anastomotic device 200 that is useful for an end-to-side anastomosis. Device 200 includes a semi-rigid anastomotic ring 202 and a harness assembly 204. The harness assembly 204 includes a semi-rigid harness ring 206 and a pair of flexible members 208 secured thereto. The harness assembly 204 can include connecting portions 209 extending laterally from the flexible members 208 to the harness ring 206. The anastomotic ring 202 includes a tapered outer surface 210 and, optionally at least one filamentary member 212 extending from the anastomotic ring 202 that can be used to secure the anastomotic ring to the harness assembly 204. The harness ring 206 includes a radially overlapping portion with respect to the anastomotic ring 202 as the inner diameter of the harness ring is less than the outer diameter of the anastomotic ring.

In operation, device 200 is used by first placing a first vessel segment 214 through the harness ring 206 and the anastomotic ring 202. A portion 216 of the first vessel segment 214 is everted over the anastomotic ring 202. A hole 217 is then cut in a second vessel 218 by means of a puncher using techniques well known to those of ordinary skill in the art (FIGS. 9A, 9B). The hole 217 has a surface 219 that is tapered inwardly from the adventitia to the intima. The hole 217 has a diameter slightly smaller than the diameter of the anastomotic ring 202.

The everted portion 216 is then placed into the hole formed in the second vessel 218. The harness assembly 204 is cinched down to the second vessel 218 by the flexible members 208 in conjunction with locking mechanisms 220. As the harness assembly 204 is secured to the second vessel, the overlapping portion of the harness ring 206 and anastomotic ring 202 retains the everted portion 216 of the first vessel in sealed engagement in the hole in the second vessel. The optional filamentary members 212 can then be used to secure the anastomotic ring to the harness assembly 204 and vessel and the connecting portions 209 cause the harness and anastomotic rings 206,202 to conform to the annular outer surface of the second vessel 218.

For a substantially perpendicular end-to-side anastomosis of the first and second vessels 214,218, the hole 217 and corresponding harness and anastomotic rings 206,202 will be annular. If the first vessel 214 is to be anastomosed at an

angle with respect to the second vessel 218, the formed hole 217 and corresponding rings 206,202 will be generally oval in shape.

The anastomotic junction of the first and second vessels 214,218 must not leak in order to achieve a successful anastomosis. The anastomotic device 200 can include additional features to assist in sealing the vessels. For example, a type of bio-sealant 211, of the type known to one of ordinary skill in the art, can be placed under and in the area of the harness ring 206 to seal the harness ring and the anastomotic ring 202 and/or first vessel. Also, the harness assembly 204 can include tissue-penetrating teeth 225, which can be barbed, to secure and seal the harness assembly and the second vessel 218. In addition, the harness ring 206 can include a surface feature, such as a ridge, to enhance sealing engagement with a surface feature in the opposing surface of the anastomotic ring 202. Various complementary surface features on the harness assembly 204 and the anastomotic ring 202 can be also be used. A further sealing enhancement utilizes one or more surgical clips for grasping a portion of the first vessel 214, the harness ring 206, and/or the second vessel 218. In a still further embodiment, the portion of the vessel everted over the anastomotic ring 202 can extend further so as to be engaged by the harness ring. The harness and anastomotic rings 206,202 can include one or more complementary surface features 221 that can penetrate through the everted portion of the first vessel and secure the harness and anastomotic rings together.

The sutureless anastomotic device of the present invention can be used both in open surgery and in closed surgery, such as laparascopic surgery. Such closed surgical techniques provide significant advantages over more invasive, open surgical techniques where much larger incisions are required. The benefits of closed surgery include reduced recovery time, decreased pain or discomfort and a considerable cost savings. Another important advantage of the sutureless anastomotic device of the present invention is the reduced time required to anastomose vessels as compared with known suturing techniques. This reduction in time significantly reduces risk to the patient and increases the success rate of surgical procedures.

The exovascular device provides further advantages over sutures. The device can be anchored to healthy adventitia whereas sutures must penetrate plaque layered

on the intima of the vessel, risking dislodgement of chunks of plaque.

One of ordinary skill in the art will realize further features and advantages of the invention from the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All references cited herein are expressly incorporated by reference in their entirety.

What is claimed is:

1. An anastomotic device, comprising:

a flexible member having a first end and a second end and first and second surfaces, the flexible member being formable into a loop of an adjustable size; and

one or more anchoring elements mounted upon the flexible member, each anchoring element having at least one tissue penetrating protrusion formed on one surface thereof.

2. The anastomotic device according to claim 1, wherein at least one of the anchoring elements is slidably mountable upon the flexible member.

3. The anastomotic device according to claim 1, further including a locking mechanism disposed on one of the first or second ends of the flexible member, the locking mechanism including an opening formed therein for receiving the other of the first or second ends of the flexible member.

4. The anastomotic device according to claim 3, wherein the locking mechanism is immovably affixed to the first end of flexible member.

5. The anastomotic device according to claim 3, wherein the opening of the locking mechanism includes at least one surface feature and one of the first or second surfaces of the flexible member includes a plurality of surface features, the at least one surface feature of the locking mechanism being engageable with a respective one or more of the surface features on the flexible member.

6. The anastomotic device according to claim 5, wherein the at least one surface feature of the locking mechanism and the plurality of surface features of the flexible member allow only unidirectional movement of the flexible member with respect to the locking mechanism.

7. The anastomotic device according to claim 6, wherein the surface features of the flexible member are mounted on the first surface of the flexible member, and comprise teeth-like members having a first surface ramped with respect to a longitudinal axis of the flexible member and a second surface orthogonal with respect to the longitudinal axis of the flexible member.

8. The anastomotic device according the claim 7, wherein the teeth-like surface features of the flexible member permit only unidirectional movement of the flexible member within the locking mechanism, the unidirectional movement taking place in direction to enable only a decrease in the diameter of the loop.

9. The anastomotic device according to claim 1, wherein the at least one tissue-penetrating protrusion of the anchoring member is oriented such that it projects radially inwardly on the loop.

10. The anastomotic device according to claim 1, wherein the at least one tissue-penetrating protrusion forms an acute angle with respect to a radial centerpoint of the loop.

11. The anastomotic device according to claim 1, further including at least one spacer element disposed on the flexible member between adjacent anchoring elements.

12. The anastomotic device according to claim 11, wherein the at least one spacer element is slidably mounted to the flexible member.

13. The anastomosis device according to claim 11, wherein the at least one spacer element is a tubular member having an inner, axial opening that is configured and dimensioned to receive the flexible member.

14. The anastomotic device according to claim 11, wherein the at least one spacer element is flexible.

15. The anastomotic device according to claim 1, wherein the anchoring element is a substantially tubular member having an axial opening formed therein that is configured and dimensioned to receive the flexible member.

16. An anastomotic device, comprising:

a flexible member having a first end and a second end and first and second surfaces;

a locking mechanism secured to one of the first or second ends, the locking mechanism having at least one opening therein for receiving the other of the first or second ends such that the locking mechanism facilitates the formation of a loop having an adjustable size; and

one or more anchoring elements mounted upon the flexible member, each anchoring element having at least one tissue penetrating protrusion formed on one surface thereof

17. An exovascular anastomotic device, comprising:

a flexible member having first and second ends and first and second surfaces, the member having a locking mechanism formed on the first end thereof, the locking mechanism including an opening formed therein through which the second end of the flexible member is inserted to form a loop of an adjustable diameter;

a plurality of projections formed on one of the first or second surfaces of the flexible member, the projections cooperating with the locking mechanism to permit the second end of the flexible member to move relative to the locking mechanism in one direction to effect a decrease in the diameter of the loop;

one or more anchor members, each having a body defining an axial opening within which the flexible member is disposed to slidably mount the anchor members on the flexible member; and

at least one tissue penetrating projection formed on an inwardly facing surface of each anchoring member.

18. The device according to claim 17, further comprising at least one spacer member slidably disposed on the flexible member between at least two adjacent anchoring members.

19. An anastomotic device for anastomosing an end of a first vessel to a side of a second vessel, comprising:

an anastomotic ring adapted to be disposed about an end of the first vessel;

a harness assembly including a harness ring having a radially overlapping portion with respect to the anastomotic ring;

at least one flexible member secured to the harness ring, the at least one flexible member forming a loop of adjustable size.

20. The anastomotic device according to claim 19, further including a locking mechanism mounted on the at least one flexible member.

21. The anastomotic device according to claim 19, wherein the anastomotic ring is tapered about a circumferential outer surface.

22. A method for conducting a sutureless anastomotic procedure, comprising the steps of:

providing a sutureless anastomotic device including a flexible member in the form of a loop having an adjustable diameter, at least one anchoring element having an inwardly projecting tissue penetrating member;

placing an end of a first vessel segment within the loop;

overlapping portions of the end of the first vessel segment and an end of a second vessel segment; and

applying an axial force to a first end of the flexible member to reduce the diameter of the loop such that the tissue penetrating members penetrate the overlapping portions of the first and second vessels to anastomose the first and second vessel.

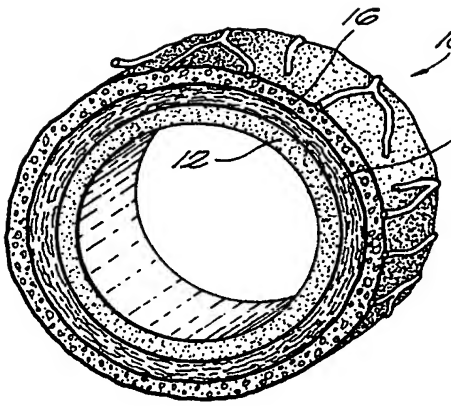

FIG. 1
(PRIOR ART)

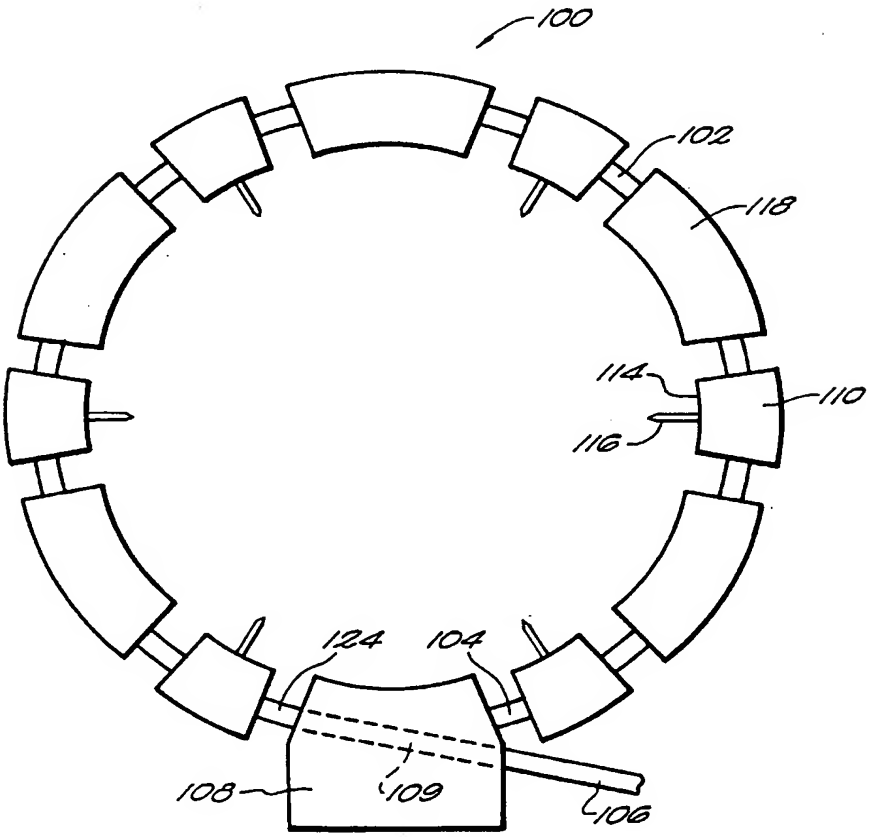

FIG. 2

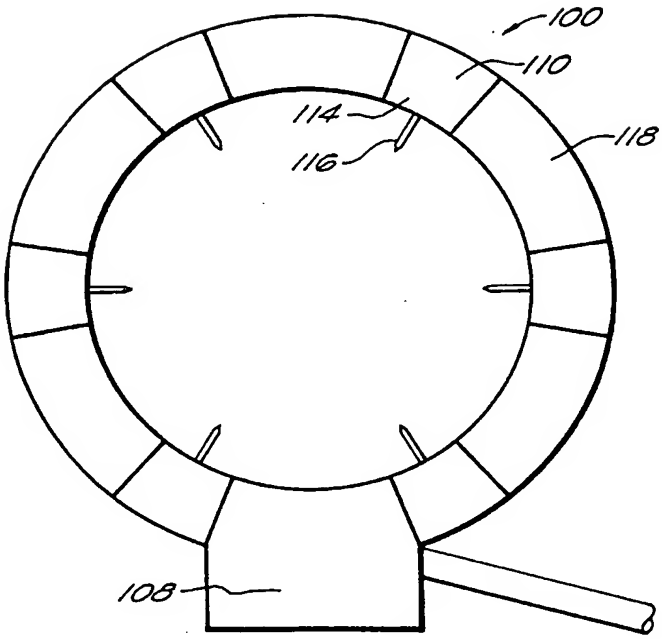

FIG. 3

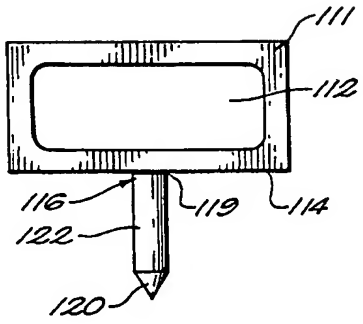

FIG. 4

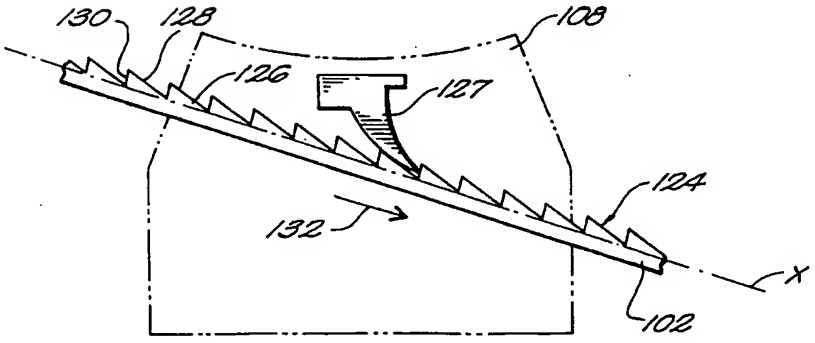

FIG. 5

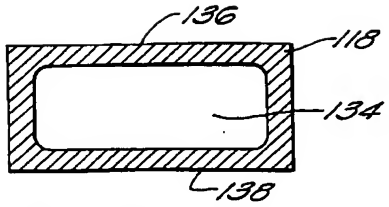

FIG. 6

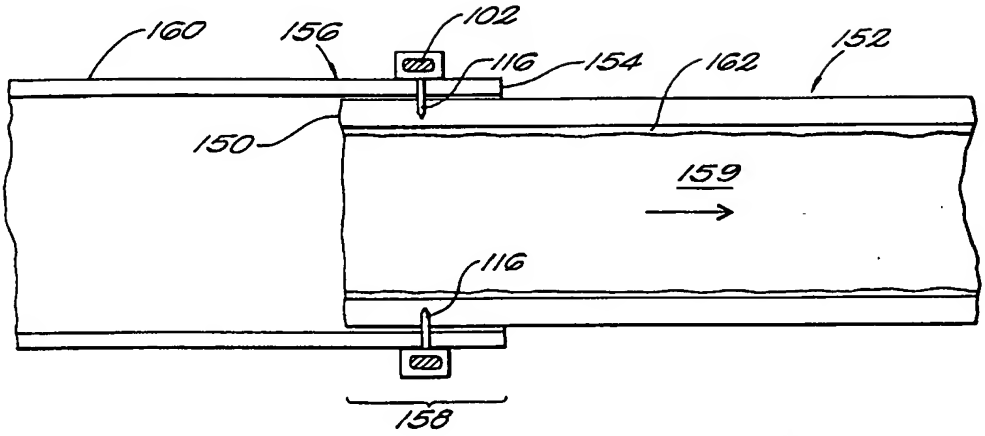

FIG. 7

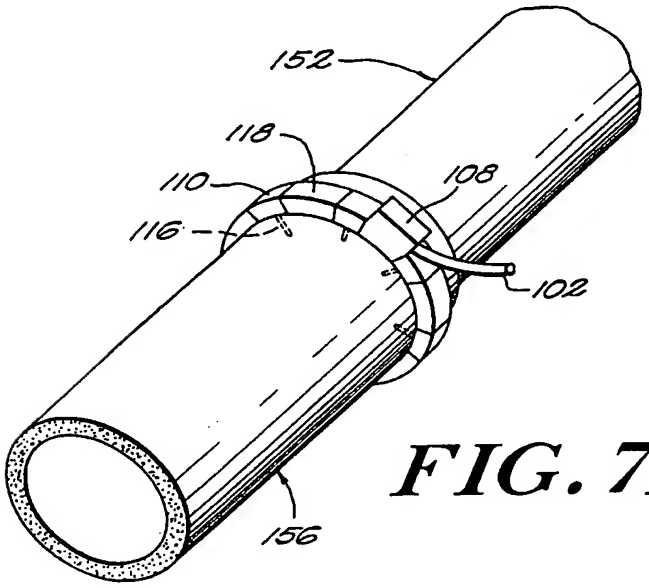

FIG. 7A

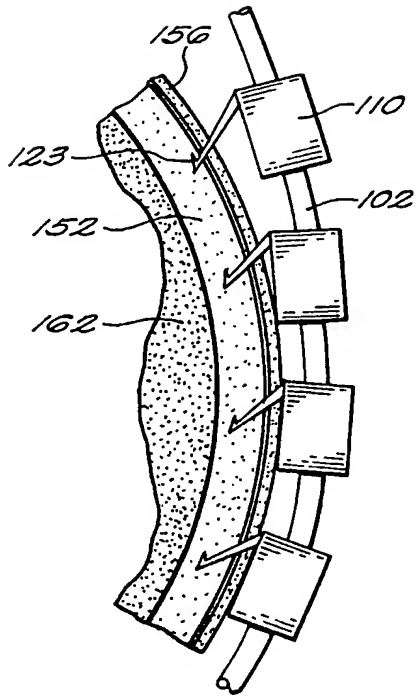

FIG. 7B

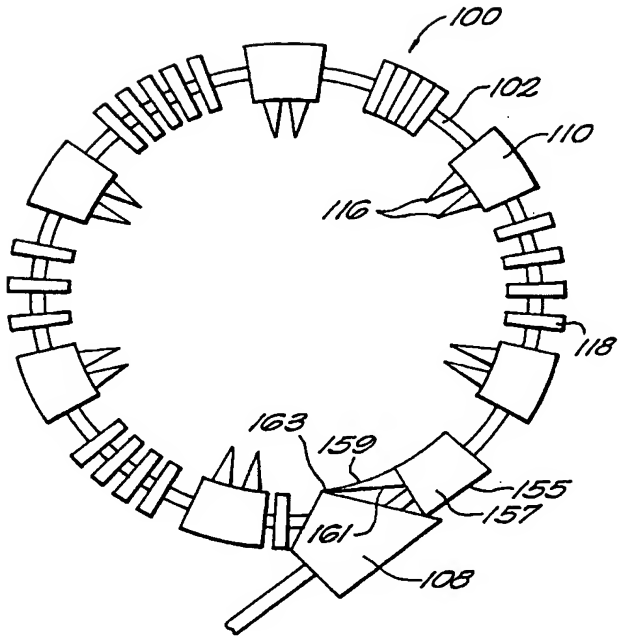

FIG. 7C

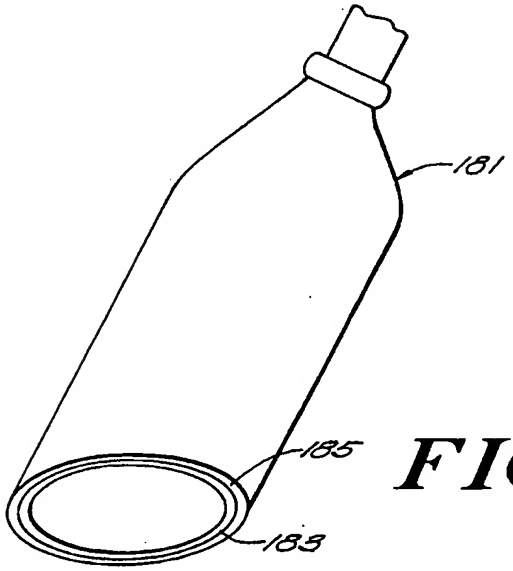

FIG. 7D

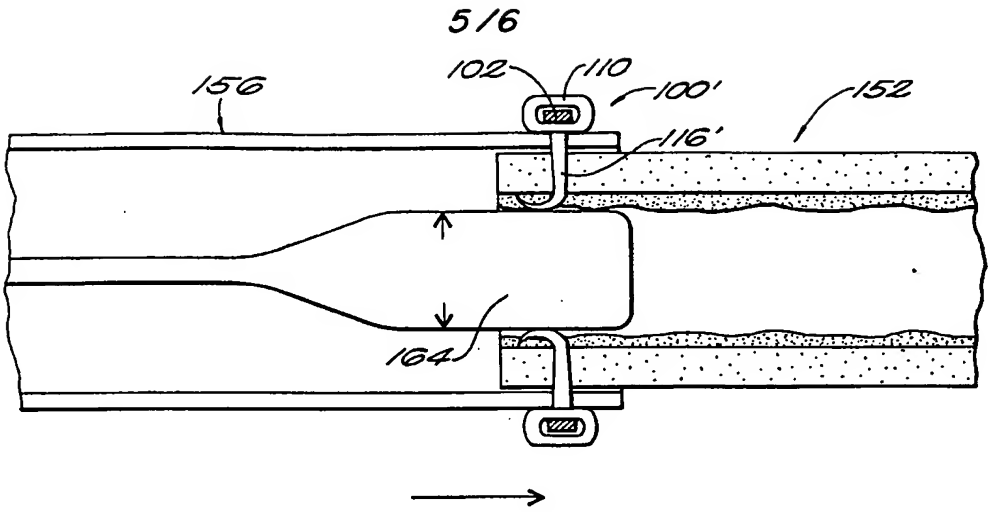
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FIG. 8

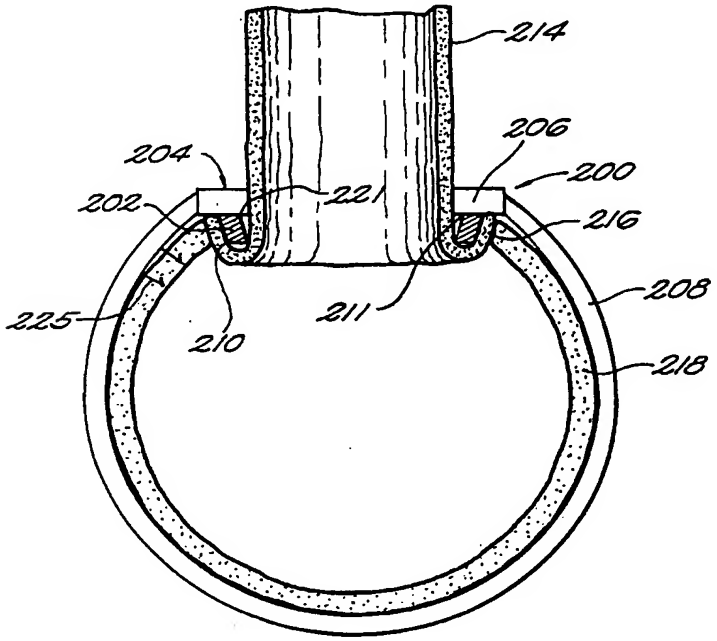
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FIG. 9

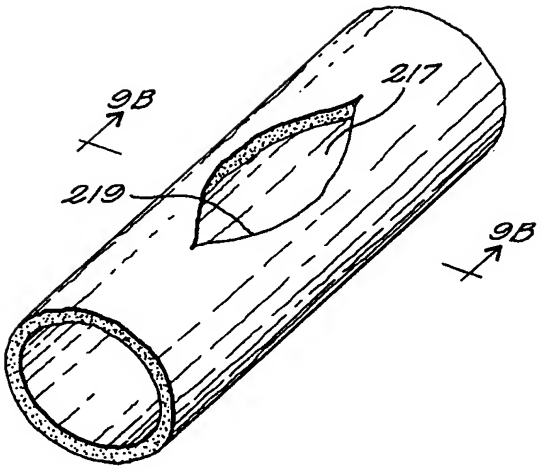

FIG. 9A

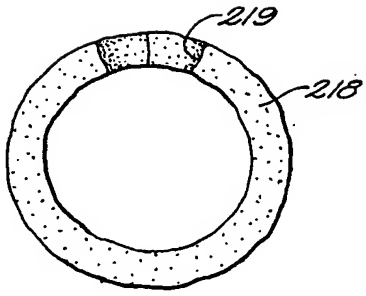

FIG. 9B

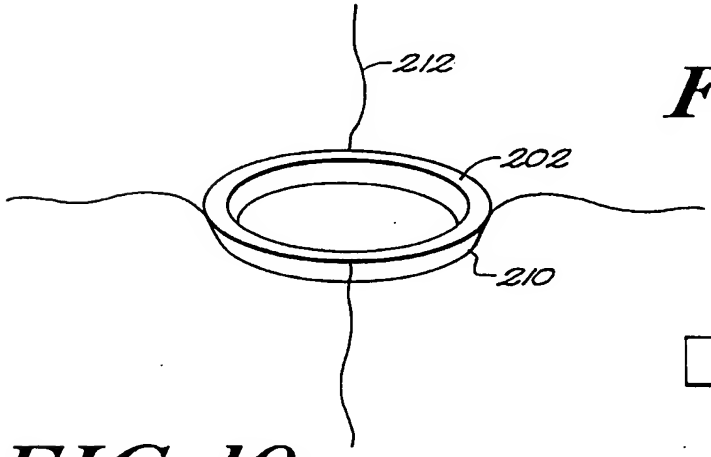

FIG. 10

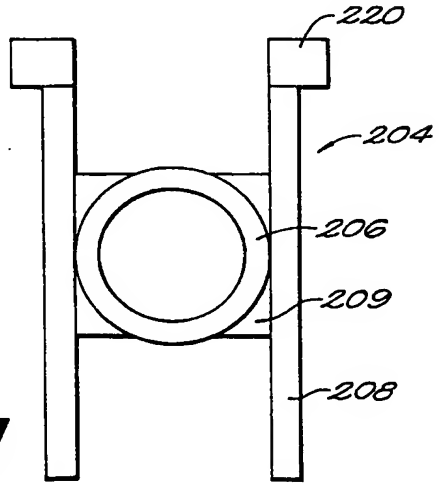

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/04387

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 17/04
US CL :606/151, 153
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139, 151, 153

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,693,249 A (SCHENCK et al) 15 September 1987, col. 2 lines 21-53.	1-22
A	US 5,234,447 A (KASTER et al) 10 August 1993, col. 7 lines 21-57.	1-22
A	US 5,486,187 A (SCHENCK) 23 January 1996, col. 3 lines 41-65.	1-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61J 2/06, 2 /00, A61B 17 /11 — A2

(11) International Publication Number: **WO 98/32412**

(43) International Publication Date: 30 July 1998 (30.07.98)

(21) International Application Number: PCT/US98/01310

(22) International Filing Date: 23 January 1998 (23.01.98)

(30) Priority Data:
60/036,359 24 January 1997 (24.01.97) US

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(74) Agents: ARRETT, Oliver, F. et al.; Vidas, Arrett & Steinkraus, Suite 2000, 6109 Blue Circle Drive, Minnetonka, MN 55343–9131 (US).

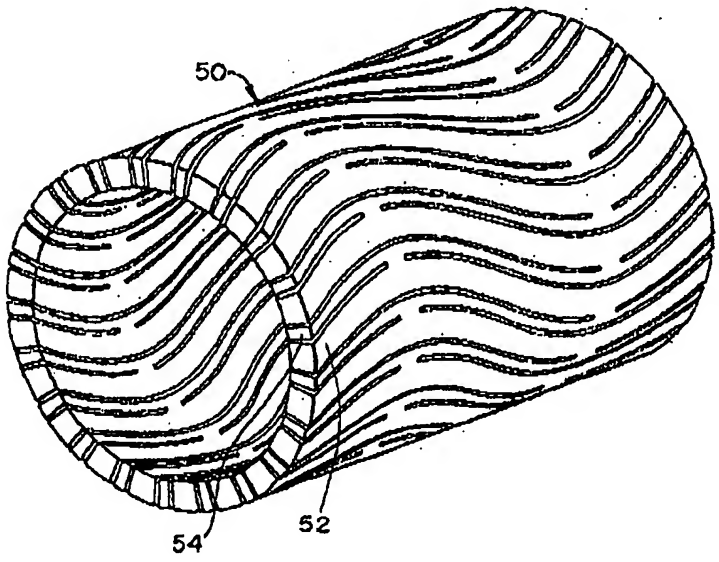
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: BISTABLE SPRING CONSTRUCTION FOR A STENT AND OTHER MEDICAL APPARATUS

(57) Abstract

The present invention is directed to bistable cells and their use in devices, particularly medical devices such as stents, clamps and valves. An expandable stent formed of a plurality of bistable cells is described. The stent has two or more stable configurations, including a first stable configuration with a first diameter and a second stable configuration with a second, larger diameter. A valve comprising a bistable cell for use in eliminating incontinence is also disclosed.



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BISTABLE SPRING CONSTRUCTION FOR A STENT AND OTHER MEDICAL APPARATUS

Background Of the Invention

There are several kinds of stents on the market with either balloon expandable or self expanding function. Balloon expandable stents are generally made from a material that can easily be plastically deformed into two directions. Before insertion, the stent is placed around the balloon section at the distal end of a catheter and pressed together to reduce the outer dimensions.

As soon as the stent is brought into the body in the proper axial position it can be expanded and thereby plastically deformed by pumping up the balloon. In this final position, the stent is at its largest diameter and should function to support the surrounding tissue, preventing an undesired shape change into a much smaller diameter, at least locally.

Therefore, the stent needs to have sufficient rigidity in the radial direction, but also some flexibility in the axial direction when it is in the final position. Further, the amount of material should be as small as possible and in the inner surface of the stent should not obstruct the flow through the channel (e.g., for blood) or cause too much turbulence.

Problems that generally occur with these stents are as follows: After compressing the stent to its smallest diameter around the balloon, the stent will always have some elastic spring back to a slightly larger diameter, which can cause problems when the catheter is brought into the patient's body. In addition, the axial friction between balloon and stent can become so small that the stent slips off the catheter. Further, a larger size stent is typically a disadvantage.

A further problem is the so called recoil of these stents. This means that after expansion by the balloon pressure, the outer diameter will always become slightly smaller as soon as the balloon is deflated. This degree of recoil can be as much as 10%, which can cause migration of the stent.

A different type of stent is made of a more or less elastically expanding

structure, which has to be held on the catheter by some external means. An example of this type is a stent that is held in its constrained state by a delivery sheath, that is removed at the moment that the stent should deploy to its natural form.

Some of these stents are made of shape memory material with either superelastic behavior or temperature sensitive triggering of the expansion function.

A disadvantage of these self-expanding stents is the need for the delivery sheath, causing a larger insertion diameter. The removal of the sheath also requires a sheath retraction mechanism, which has to be activated at the proximal end.

Most stents of both types further have the disadvantage of relatively large length change during expansion and a poor hydrodynamic behavior because of the shape of the metal wires or struts.

Another disadvantage of some stents is the positive spring rate, which means that further expansion can only be achieved by higher balloon pressure.

The construction of prior stents is typically made in such a way that the external forces, working on the stent in the radial direction, merely cause bending forces on the struts or wires of the structure.

For example, a unit cell of a Palmaz-Schatz-stent, as produced by Johnson & Johnson Interventional Systems or the ACT One Coronary stent, produced by Progressive Angioplasty Systems, Inc. has in its collapsed condition a flat, rectangular shape and in its expanded condition a more or less diamond-shaped form with almost straight struts (Palmaz-Schatz) or more curved struts (ACT-One).

The shape of the unit cell of such stents is typically symmetrical with four struts each having the same cross section. In addition, the loading of the cell in the axial direction will typically cause an elastic or plastic deformation of all of the struts, resulting in an elongation of the unit cell in the axial direction. These unit cells have a positive spring rate. In stents based upon these unit cells the stability against radial pressure is merely dependent on the bending strength of the struts and their connections.

Summary Of the Invention

In this patent application a new type of stent is described with a unit cell, having a negative spring rate and a bistable function. Such a unit cell can also be used in

other medical applications. This means that it has two configurations in which it is stable without the need for an external force to hold it in that shape. The unit cell is formed using at least two different sections. One section is less pliable than the other one and acts a relatively rigid support that hinders the shape change of the more pliable section in one direction. In the other direction the pliable section can be deformed, but because of the opposing force from the rigid section, the stability of the pliable or flexible section is strongly increased.

External forces in a direction perpendicular to the most pliable section are distributed to the rigid section and the cross section of the pliable section is merely loaded in compression mode. This makes the construction much stronger than prior stents. In prior stents, all struts have generally the same cross section and mechanical properties and are merely used in the bending mode.

The construction of a stent, based upon this unit cell results in an apparatus, that can easily be elastically compressed around the balloon by finger pressure.

Below a certain critical diameter, the present stent snaps further to a stable, smallest diameter, thus holding the deflated balloon firmly on to the surface of the catheter, with an insertion diameter that is as small as possible. An additional sheath is not required, but may be used for extra safety.

After the stent has been brought into the patient's body at the proper axial position, the balloon can be inflated until the stent reaches its critical elastic equilibrium diameter. Slightly above this diameter the stent automatically expands further to its final largest diameter, where it reaches its maximum stability against radial pressure. The design enables a constant length large expansion ratio, a reliable expandability and/or a small surface ratio.

A further embodiment of this invention is the possibility of a kind of stepwise expanding stent with a range of stable diameters.

Another part of the invention is a stent with several external diameters along its length, to adapt as good as possible to the shape of the body cavity where it is placed.

Another part of the invention is the possibility to modify the stress and strain pattern in the unit cell by means of a heat treatment in such a way, that the force

displacement characteristic of this unit cell becomes asymmetrical or even exhibits a monostable instead of a bistable function, either with the expanded diameter or the collapsed diameter being the most stable condition.

Another embodiment of the invention is the modification of the geometry of the cross section of some struts to achieve the symmetric or asymmetric bistable or monostable force against displacement characteristics of a unit cell.

Another part of the invention is the use of one or more unit cells in other medical applications such as, for example, an expander or a clip, either to spread a body cavity open or to clamp or hold a body part or some body tissue.

The invention is also directed to the use of the inventive stents in conjunction with inventive expander rings to join together two vessels.

The invention is also directed to a bistable valve having a snap-action bipositional unit cell and uses for the same, in particular, to prevent incontinence.

The invention is also directed to multistable cells and their use in medical devices.

Description of the Construction.

The construction of the present stent includes a series of elements with an arrangement of unit cells that enable the stability in a special way. Each unit cell exists out of at least two distinct, mechanically connected sections with different mechanical behaviors. One section acts as a relatively rigid support for the more flexible counteracting section. The more flexible section is responsible for most, if not all, of the expansion of the stent. There are several ways to manufacture a stent based upon this principle and it can be made from several materials, like polymers, composites, conventional metals or shape memory alloys with superelastic behavior or with temperature sensitive behavior.

It can be made from an arrangement of wire or strip, welded together at specific places. Another possibility is metal deposition in the desired pattern onto a substrate or the use of sintering of prealloyed powder.

A further method is making the stent from a tubular shaped starting material, with a pattern of slits or slots made in the wall by means of etching, grinding,

cutting (e.g., with a laser, water, etc.), spark erosion or any other suitable method. The pattern can also be made in a flat plate and then welded, brazed or crimped to a more or less cylindrical shape or a cylindrical mid section with two conical ends with larger diameters.

Brief Description of the Drawings

Fig. l shows the principle of a bistable mechanism;

Fig. 2 shows the force-displacement characteristic of the mechanism of Fig. l;

Fig. 3 shows another bistable mechanism with an asymmetric bistability;

Fig. 4 shows the force-displacement characteristic of the mechanism of Fig. 3;

Fig. 5a shows an inventive tubular stent in the stable, fully collapsed configuration;

Fig. 5b shows an inventive tubular stent in the stable fully expanded configuration;

Fig. 6 shows a part of a stent with one bistable unit cell, drawn in the stable expanded shape;

Fig. 7 shows the part of the stent of Fig. 6 near its elastic bistable equilibrium position;

Fig. 8 shows the part of the stent of Figs. 6 and 7 in its stable collapsed shape; and

Fig. 9 shows a larger section of the stent of Figs. 6 and 8, showing some unit cells in the collapsed shape and some unit cells in the expanded shape.

Fig. 10 shows an inventive stent formed of a plurality of smaller inventive stents joined together with flexible connectors.

Fig. 11 shows a partially expanded inventive stent having more than one type of bistable unit cell;

Fig. 12 shows an inventive stent having a range of diameters along its length;

Fig. 13 shows an inventive expansion ring in expanded state;

Fig. 14 shows the expansion ring of Fig. 13 in contracted state;

Fig. 15 shows an inventive stent joining two vessels together and further secured with inventive expansion rings, the stent exterior to the vessels;

Fig. 16 shows a cross-sectional view of Fig. 15 along section line 16-16;

Fig. 17 shows an inventive stent joining two vessels together, the stent interior to the vessels;

Fig. 18 shows two vessels joined together with an inventive expansion ring and a clamp

Fig. 19 shows a bistable valve in the closed position;

Fig. 20 shows the bistable valve of Fig. 19 in the open position;

Fig. 21a shows a multistable cell in the fully contracted state;

Fig. 21b shows the multistable cell of Fig. 21a in the fully expanded state;

Fig. 22a shows another multistable cell in the fully contracted state;

Fig. 22b shows the multistable cell of Fig. 22a in the fully expanded state;

Fig. 23 shows several unit cells as shown in Figs. 21a,b joined together and in the fully expanded state;

Fig. 24a shows several unit cells as shown in Figs. 22a,b joined together and in the contracted state;

Fig. 24b shows the interconnected cells of Fig. 24a in fully expanded state;

Fig. 24c shows the interconnected units cells of Fig. 24a in the process of expanding; and

Fig. 24d shows several strips of interconnected cells as in Figs. 24a,b joined together and in the process of expanding.

Detailed Description of the Drawings

Fig. 1 shows the principle on which the stent is based, Fig. 1a shows a rod 1 with a length L, which is compressed in its axial direction unit; it reaches its buckling stress. Then the central part of the rod will bend out in a sidewards direction, either to position 2 or 3 (dashed lines in Fig. 1b). When the axial displacement L of the ends of the rod is held stable by external clamps 4, it is possible to move the central section of

the rod between the two stable positions 2 and 3. This movement is in a direction X, perpendicular to the original length axis A-A of the rod. All positions between the stable positions 2 and 3 are unstable. In Fig. 1b the central part of the rod has to rotate over an angle β before the rod can be moved in direction X. Fig. 1C shows a second order curvature in rod 1, which occurs when the rotation over angle β is opposed by clamping the central part of rod 1 and maintaining this part parallel to the axis A-A.

Fig. 2 shows the force F as a function of displacement X, with X displayed in the horizonal direction. The rod is moved from the upper 2 to the lower 3 stable position of Fig. 1. The force increases rapidly from zero to Fmax. At that moment the onset of either the first or second order curvature of Fig. 1b and 1c is reached. Further displacement in direction X costs less force, because this spring system has a negative spring rate. The force even becomes zero in the mid position and further movement occurs automatically. It can be seen in Fig. 2 that the system is completely symmetrical and the force needed to move back from the lower to the upper position has the same characteristic.

Fig. 3 shows rod 5, which will have an asymmetrical force displacement characteristic, because it already has a preset curvature, even in the unloaded position, where the length is already L-ΔL. This can be achieved by prior plastic deformation, heat treatment or the use of an asymmetrical geometry of the cross section of the rod (not shown). The rod 5 in Fig. 3 can be mounted between two clamps on a length L - ΔL, and if it is elastically deformed in the same way as the rod in Figs 1b and 1c, it will have a different stress distribution in the cross section in end position 2 and 3, compared to the rod of Fig. 1. This means that the rod has become a preferent unloaded stable position, shown in Fig. 3.

Fig. 4 shows the asymmetrical force-displacement characteristic of the precurved rod of Fig. 3. The initial displacement from the stable upper position needs a starting force F1 and if the rod is in its stable lower position the starting force in the opposite direction is only F2, being smaller than F1. Force F2 can be made as small as desired, even zero or negative, but needs to have a positive value if stability of the lower position is required.

Figs. 5a and 5b show the general appearance of an inventive tubular stent

in fully contracted and fully expanded configuration respectively. The stent, in its fully contracted state shown generally at 50 and in its fully expanded state shown generally at 60, is comprised of a plurality of interconnected bistable unit cells (shown in the expanded state at 64 in Fig. 5b). The bistable unit cells are formed from a first relatively rigid segment 52 (66 in Fig. 5b) and a second relatively flexible segment 54 (68 in Fig. 5b), joined together at ends 70 and 72. Second relatively flexible segments 68 are interconnected with adjacent relatively rigid members 66. Adjacent cells in the longitudinal sense (the longitudinal axis is denoted by reference numeral 75) are joined at ends 70 and 72. By applying a uniform radially outward or inward force, the stent may be switched directly from a fully contracted to a fully expanded configuration or vice versa.

Fig. 6 (corresponding to inset 6 in Figure 5b) shows a small part of a stent such as that shown in Figs .5 which uses the bistable function of a unit cell, according to the present invention. The drawing shows a horizontal line A-A, which is parallel to the central axis of the stent. There are two series of sinusoidal segments with distinct size (see also Fig. 9 for an overview). The segments 7 and 9 have a relatively large cross section. Only segment 9 is shown entirely. The segments 9 and 10 have a relatively smaller cross section, and here only segment 8 is entirely shown. The segments are interconnected for example welded, at joints 11 and 12.

Because of the difference between the cross section of segment 8 and 9. the deformation force of segment 8 is much lower than for segment 9. Therefore, segment 9 can be considered as a relatively rigid clamp, like the clamps 4 in Fig. 1b opposing relative displacement between the joints 12 in the axial direction, parallel to axis A-A. In contrast, segment 8 acts as a flexible rod, like rod 1, described in Fig. 1 or rod 5, described in Fig. 3. This combination of segments 7 and 8 or 9 and 10 defines a unit cell, acting as a bistable spring system with a force-displacement curve F-X like the described curves of Fig 2 and 4, depending on the unloaded condition and geometry of the segments. Alternatively, instead of using segments or struts of different diameter, the segments can have the same diameters (i.e., cross sectional area) and exhibit different strengths or rigidity and still accomplish the same effect. One way to obtain such differences in strength or rigidity would be to use different materials for the segments.

Another way would be to use the same material, like a metal, for all the segments but selectively strengthen (e.g., by heat treating) those segments that need to be rigid. It should be noted that heat treatment will not strengthen all materials. Nitinol, for example becomes more pliable as a result of heat treatment. This property of Nitinol can be exploited, however, to render one section of Nitinol more pliable relative to a second, non-heat-treated section of Nitinol.

Fig. 7 shows the same part of the stent (as depicted in Fig. 6) near the elastic equilibrium position. Segment 8 has been deformed into the direction X, caused by force F, but segment 9 has almost its original shape, because of its larger rigidity.

Fig. 8 shows the same unit cell of the stent of Figs. 6-7 after it has been pressed through the elastic equilibrium position. It automatically snaps into its stable position of Fig. 8. This snapping force can be strong enough to hold a deflated balloon tight on the catheter shaft (not shown), depending on the mechanical characteristics (e.g., the strength) of the material(s) used to make the segments. With the geometry shown in these figures, the segments 8 and 9 fit close together, taking up a minimum amount of space when the stent is in its smallest stable diameter.

Fig. 9 shows a section of the stent of Figs. 5, flattened for illustrative purposes, showing several flexible segments in the collapsed stable shape (segments 14, 18 and 20) and one segment element 16 in the expanded stable shape. Segments 13, 15, 17, and 19 are relatively rigid segments and substantially maintain their original shape. The distance between two relatively rigid segments is shown as (h) in the collapsed stable shape and (H) in the expanded stable shape. The value of the displacement (H-h) in the direction X depends on the height of an expanded unit cell or amplitude of the segments and the size of the connecting joints. The described part of the stent is shown as a flat surface, but it may be clear that a cylindrical stent such as that shown in Figs. 5 is shaped if segments 13 and 20 are directly connected to reach other with joints 21. In other words, the stent is shown separated along the joints 21 and in a flattened condition.

The range of stable diameters of the stent changes with the value $(H-h)/\pi$, each time that a flexible segment snaps from the collapsed stable position to the expanded stable position. The result is a stent with an extremely rigid surface at all diameters being able to withstand the external forces better than with conventional stents.

In the length direction, the flexibility of the stent can be increased by disconnecting several unit cells from their neighbor unit cells, for example, by cutting the center of one or more joints while maintaining the several joint pieces as joints.

Another method to increase flexibility is to change the geometry of several sections of the unit cells in the length direction from the relative flexible to the relative rigid shape several times along the total length of the stent. In other words, referring to Fig. 9 one or more or each of the segments 13 - 20 could be constructed with larger and smaller diameter (or otherwise flexible and rigid) sections which alternate after each joint 21.

Another possibility, as shown in Figure 10 is the use of a series of short multistable stents 100 aligned lengthwise end to end and connected with flexibility joints 104 having the same or a different geometry or configuration as the joints forming individual unit cells.

The scope of the invention should include all types of material. One of the most interesting materials is superelastic Nitinol, because of its large elastic strain, well defined stress values, caused by their plateau stresses and the possibility to define the desired curvature into the metal by means of a heat treatment. A stent of Nitinol can be made by forming slits or slots in a tube, while in its collapsed or smaller stable diameter. The slotted tube is then expanded by a separate shaping tool and heat treated on this tool to define the expanded stable diameter as the unstrained shape.

In a more general sense, the present invention is directed to a device having a plurality of stable configurations. The device is comprised of a plurality of interconnected multistable cells. The cells include one or more relatively rigid sections and one or more relatively flexible sections interconnected so as to define a cell structure in the form of a multistable spring system having a plurality of stable configurations. In a preferred embodiment, the cells comprise a first arcuate member having first and second ends and a second arcuate member having first and second ends, the first end of the first member in communication with the first end of the second member, and the second end of the first member in communication with the second end of the second member. It should be noted, however that members need not be rigorously arcuate. Other shaped members, including relatively straight members are contemplated as well.

The invention, in particular, contemplates bistable cells, that is cells having two stable configurations. In one such cell, the distance between corresponding points on the first and second sections is larger in the first stable state of the cell than in the second stable state of the cell. The cells themselves are constructed and arranged so that the device itself is at least bistable and possibly multistable. One such device, a cylindrical stent having two or more configurations with an initial diameter size and a final larger diameter size has been described above. However, multistable stents are also contemplated. Thus, for example, a stent may be constructed in which the cells are designed and arranged to provide a range of diameters in step-wise fashion. One such way this may be accomplished would be to employ several different types of cells in the stent, each type of cell having a different spring constant so that depending on the amount of force used, the stent would assume a different diameter. Such a stent in a partially expanded state is shown schematically in Fig. 11. A partially expanded stent is shown generally at 120. The stent is comprised of relatively rigid segments 123, 127, 131 and 135 which substantially maintain their original shape, and relatively flexible segments 125, 129, and 133. The segments are interconnected, with joints 122. As depicted, first flexible elements 125, and 133 are in an expanded configuration while second flexible element 129 is in a contracted configuration. By applying a radially outward or tangential force, flexible element 129 may be flipped to its fully expanded configuration resulting in a stent (not shown) with a larger diameter. As shown in Fig. 11, cells 138 are larger than cells 136 even in the contracted state. First flexible elements 125 and 133 are characterized by a different degree of flexibility than second flexible element 129.

Another form of stent, as shown generally at 150 in schematic Fig. 12, has an first diameter at a first end 152, a second diameter at a second end 154 and one (or more) intermediate diameters in a region 156 between first end 152 and second end 154, the intermediate diameter differing from the first and second diameters. The interconnected cells in such a stent, as shown generally at 150 in Fig. 12 may all have the same force constant and hence be openable all at once with the application of the necessary force or there may be several different types of cells, each with their own force constant. In order to achieve the multiplicity of diameters, cells of differing sizes may be

used. In one embodiment of this type of stent, the first and second diameters are the same while in another embodiment, the first and second diameters differ.

The present invention is also directed to a method of implanting an expandable stent having a plurality of stable configurations. The method comprises the steps of applying the stent to an expanding means on a catheter, delivering the stent to a desired bodily location, expanding the expanding means so as to expand the stent from a first stable configuration to a desired second stable configuration, the second stable configuration having a larger diameter than the first stable configuration, and deploying the expanded stent at the desired bodily location. The expanding means may be a balloon, a mechanical device on or in the catheter, a heat source where the cells can be induced to change states by heating or any other suitable expanding means. The stent may be applied to the balloon in the first stable configuration or may be applied in the second stable (expanded) configuration during the applying step. In the latter case radially inward pressure may be applied to the stent so as to urge the stent into the first stable configuration to snap it onto the catheter. Where the stent has additional stable states, the stent may be applied to the balloon in an intermediate stable state in which the diameter of the stent is intermediate between the diameter in the first state and the diameter in the second state. Again, the stent may be locked on the expanding means by further applying a radially inward pressure.

A further object of the invention is the use of a single bistable unit cell as an expander (expansion ring), that can be brought into a narrow place and then triggered to snap back into its expanded stable shape. As shown in Fig. 13 an expansion ring shown generally in its expanded state at 250 consists of a first rigid member 254 having first 258 and second 262 ends and a second more flexible member 266 having first 270 and second 274 ends. First end 258 of first member 254 is connected to first end 270 of second member 266 and second end 262 of first member 254 is connected to second end 274 of second member 266. Fig. 14 depicts the expansion ring of Fig. 13 in its contracted state. Second member 266 is seen to be in a second stable position.

Another object of the invention is the use of a single bistable loop (unit cell) as a clip, that can be used to clamp on an artery, fallopian tube or any other body part, to close or hold it for some time. For such a clip it may be desirable to define the

collapsed stable shape as the unstrained shape, because the collapsed stable shape has to be the most stable one. In the collapsed state, the clip would resemble the collapsed expansion ring of Fig. 14. A triggering means would be used in conjunction with the clamp to switch the bistable loop from one state to another. The triggering means may be pneumatic, hydraulic, mechanical, thermal or electromechanical means. Examples of such triggering means include a human hand applying force to the bistable loop, and the application of heat to the loop. Other triggering means include pulling on the device, pushing on the device, bending the rigid section of the device or releasing a restraint holding the flexible member in place.

Another part of the present invention involves constructions between one or more ring-shaped elements according to the present invention, combined with a tubular sleeve that is reinforced or held open with such elements. An example is a so-called graft stent made of a polymer with one or more expansion rings. The expansion rings may consist of the above-described bi-stable cells. The surface of the stent comprises a skin mounted on the expansion rings. In mounting the skin, the skin may surround, be in or between the expansion rings. The skin may be human or animal skin, a polymeric material or any other suitable bio-compatible material. Such a stent may comprise one or more expansion rings, such as a first expansion ring at a first end of the stent and a second expansion ring at a second end of the stent. The stent may be of constant diameter along its length or may have a first diameter at the first end and a second diameter at the second end.

The present invention is also directed to a stent having an unexpanded configuration and an expanded configuration, and comprising a plurality of generally longitudinal, wave-like first members characterized by a first wavelength, and having peaks and troughs and a plurality of generally longitudinal wave-like second members characterized by a second wavelength, and having peaks and troughs. The wavelengths of the first and second longitudinal members are substantially equal. The second members are capable of stably assuming two positions, a first position corresponding to the unexpanded configuration in which the first and second members are in phase and a second position corresponding to the expanded configuration, in which the first and second members are 180° out of phase. The first members are more rigid than the

second members. The first and second longitudinal members are disposed on the surface of the stent such that the longitudinal first and second members alternate. In the unexpanded state, each peak of each first member is connected to one adjacent peak of a second member in a region of attachment and each trough of each first member is attached to one adjacent trough of a second member in a region of attachment, as can be seen from Fig. 9. The regions of attachment are separated along the longitudinal direction by one wavelength. The so described stent can be snapped from the unexpanded configuration to the expanded configuration by applying a radially outward force and similarly can be snapped from the expanded to the unexpanded configuration by applying a radially inward force. While such stents may be used internal to a bodily vessel, it may also be used external to vessels to join two vessels together.

The invention also contemplates a method of joining together two vessels comprising the steps of delivering an inventive stent in an unexpanded configuration in a first stable state to a bodily site, expanding the stent to a second stable state, the diameter of the stent in the second stable state exceeding that of the vessels to be joined and placing the stent over the vessels to be joined. The stent may then be contracted to a third stable state, the stent in the third stable state having a diameter intermediate between the diameters of the stent in the unexpanded state and in the second stable state. The stent may further be secured to the vessel with the aid of one or more of the above-described expansion rings (a bistable loop). One or more expansion rings, such as that depicted in Figs. 13 and 14 or small clamping stents (such as that formed from the strip shown in Fig. 23) may be delivered to each side of the stent in a contracted state and deployed so as to clamp the vessels between the ring(s). Multiple rings may be used for additional clamping. As shown generally at 300 in Fig. 15, a first vessel 304 and a second vessel 308 are joined together with inventive stent 312. Vessel 304 overlaps stent 312 in a first overlap region 316 while vessel 308 overlaps stent 312 in a second overlap region 320. Vessel 304 is clamped between expansion ring 324 (shown in the expanded state) and stent 312 while vessel 308 is clamped between expansion ring 328 (shown in the unexpanded state for illustrative purposes only) and stent 312. the dotted lines associated with expansion ring 328 illustrate expansion ring 328 in its expanded state. It should be additionally noted that Fig. 15 provides a cut-away view of vessels showing

the rings contained therein. Fig. 16 shows a cross-sectional view of Fig. 15 along section line 16-16. Vessel 304 is shown sandwiched between stent 312 and expansion ring 324.

In another embodiment, as shown in Fig. 17, a first vessel 404 and a second vessel 408 are joined together by a stent 412. First end 416 of stent 412 rests in vessel 404 while second end 420 of stent 412 rests within vessel 408. Optional clamps (such as a small portion of a collapsible inventive stent shown later in strip form in Fig. 23) 424 and 428 residing on the outside of vessels 404 and 408 clamp the stent to the vessel. Additional clamps may be used as needed.

In another embodiment, a combination of the embodiments of Figs 15 and 17, the first end of the stent may protrude from one of the vessels and the second end of the stent may extend over the second vessel. Again, clamps and expansion rings may be used to further secure the stent to the vessels.

In another embodiment, as shown in Fig. 18, vessel 454 and vessel 458 are held together by an expansion ring 462 internal to the vessel and a clamp 466, consisting of, for example, a small section of collapsible stent, the stent chosen so that the diameter of the stent in a collapsed state affords a snug fit with vessels 454 and 458 and expansion ring 462. Either the expansion ring or the clamp, but not both, may be replaced by a suitable support such as a rigid collar.

The invention also contemplates a method of joining together two vessels comprising the steps of delivering an inventive stent in an unexpanded configuration in a first stable state to a bodily site, placing two bodily vessels over the stent and expanding the stent to a second stable state, the diameter of the stent in the second stable state exceeding that of the vessels to be joined. The diameter of the stent in the second stable state is preferably chosen so that the vessels fit snugly over the stent. The delivery of the stent may be accomplished by delivering the stent in an unexpanded configuration through a bodily vessel and subsequently expanding the stent to rest snugly in the vessels to be joined (where a portion of the stent resides in a vessel), or by expanding the stent to its most expanded state, placing the stent over the vessel and then contracting the stent to an intermediate state over the vessel. The collars and expansion rings mentioned above may similarly be delivered. Alternatively, the stent, collars and expansion rings may be delivered by surgically exposing the vessel in question.

The present invention is also directed to a bistable valve. The valve, as shown generally at 600 in Fig. 19 includes a snap-action bipositional unit cell shown generally at 604 located within a conduit 606. Snap-action bipositional unit cell 604 consists of a (substantially arcuate) flexible member 608 having a first end 612 and a second end 616. First end 612 is in communication with a triggering means 620 which is supported, in turn by a support means 624 emerging from the inner surface of conduit 606. Second end 616 of flexible member 608 is anchored to stop surface 628 which extends across conduit 606. Support means 624 and stop surface 628 must be sufficiently rigid to hold flexible member 608 in place and must be more rigid than flexible member 608. Stop surface 628 extends substantially obliquely across conduit 606 in oblique regions 630 and has a opening 632 within in longitudinal region 634 to allow the flow therethrough of a fluid. Although opening 632 is oriented along the longitudinal axis 636 of conduit 606, those of ordinary skill in the art will recognize other possible orientations of the opening and stop surface. Valve closure member 640, actuated between open and closed positions by flexible member 608, is constructed and arranged so as to block the flow of fluid through opening 632 when flexible member 608 is in the closed position. When flexible member 608 is in the open position, as depicted in Fig. 20 valve closure member 640 no longer obstructs opening 632, thereby allowing the flow of fluid therethrough.

While triggering means 620 may be any suitable mechanical, hydraulic, pneumatic, or thermal based trigger known in the art at present or in the future, in a preferred embodiment, triggering means 620 is a piezoelectric element. In operation, if the piezoelement shown in Fig. 19 at 620 is not activated, valve closure member 640 is closed. Activation of piezoelement 620, as shown in Fig. 20 causes a small shortening in the longitudinal length (denoted by Y in Fig. 15) of piezoelement 620 which in turn releases flexible member 608 from its first position. With member 608 released, valve closure member 640 is free to open under the pressure transmitted from the fluid. Member 608 assumes a second, inverted, position, as depicted in Fig. 20. While the fluid pressure maintains member 608 in its second position, even in the absence of any fluid. member 608 remains in its second position, as depicted in Fig. 20 if the triggering is turned off and piezoelement 620 assumes its original length. Valve closure member 640

may be closed again, in the absence of fluid, by a subsequent triggering of piezoelement 620 allowing member 608 to transition to its second (closed) position which is the preferred position of member 608. Member 608 has been treated to receive a preferred position as shown in Fig. 3.

The valve depicted in Figs. 19 and 20 may be applied to medical and non-medical devices. It is, in particular, an aim of the present invention to apply the inventive bistable valve to the control of urinary incontinence. In a patient with incontinence, the above described valve may be implanted in the urethra using any suitable means including the use of the above-described expansion rings to clamp the valve to the urethra. Although the valve in the default state is closed, the valve may be triggered when the bladder is full, to void the bladder. Upon voiding the bladder, the valve may be triggered again to close it. Another such application is to employ the inventive valve in conjunction with a shunt. The shunt may be activated by triggering the device and similarly may be closed by triggering the device.

Of course the valve may be used in other medical and non-medical applications as well.

In addition to the bistable unit cells disclosed above, bistable unit cells and more generally, multistable unit cells of other shapes are also contemplated by the present invention. Figs. 21a and 21b are schematic representations of another embodiment of an inventive hinged multistable cell in its contracted and expanded states, respectively. The contracted cell, shown generally at 700, and the expanded cell, shown generally at 705, consist of four interconnected relatively rigid members. Two side members 709 are connected to opposite ends of top member 713 via hinges 715. Side members 709 are connected at their opposite ends to opposite ends of bottom member 717 via hinges 719. Preferably, the hinges are elastic or plastically deformable. The hinges may be fixedly attached to the side, top and bottom members or may be integral with these members. In the latter case, the hinges may be formed by removing material from the cell in the region of the hinges so that the hinges are thinner or have a different geometry from the side, top and bottom members. In the process of transitioning from the expanded to the collapsed state, bottom member 717 opens slightly. The cell of Figs. 21a,b also has two additional intermediate states in which one or the other (but not both)

of side members 709 and top member 713 are collapsed downward.

A hexagonal hinged multistable unit cell is shown schematically in Fig. 22a in the collapsed state and in Fig. 22b in the expanded state. The cell, shown generally at 750, consists of top member 754 and bottom member 758, and upper side members 762. Two upper side members 762 are connected to opposite ends of top member 754 via hinges 756. Upper side members 762 are connected to bottom member 758 via hinges 768. Bottom member 758 is shaped like a 'U' with the two uprights of the 'U' modified to lie at oblique angles with respect to the bottom part of the 'U'. As with the previously discussed inventive cells, hinges 756 and 768 may be elastic or plastically deformable and may be fixedly attached to the members or integral with the members. The hexagonal unit cell exhibits multiple stable states. In addition to the fully expanded and fully contracted states shown in Figs. 22a and 22b, the hexagonal cell can also achieve two intermediate stable configurations in which only one of the two upper side members 762 is collapsed inward along with top member 754.

The above described hinged multistable cells may be used in any of the above discussed applications e.g. to form stents, clamps, clips, expander rings, bistable valves.

In one such application a ring or stent is formed of the hinged cells of Figs. 21a and 21b. As shown in Fig. 23, a series of unit cells of the type depicted in Figs. 21 are joined together so that the top member of a cell forms a portion of the bottom member of an adjoining cell. As depicted, top member 814 of cell 810 forms a portion of bottom element 818 of cell 820. Similarly, top member 824 of cell 828 forms a portion of bottom element 832 of cell 836. Although the ring or stent in Fig. 23 has been cut for illustrative purposes, the two ends 840 and 844 are normally joined together with a portion of lower member 848 of cell 852 serving as an upper member for cell 856. The ring so formed has a range of stable stable states including a fully expanded state and a fully contracted state. Where the individual cells are made identically, only the fully expanded states may be accessed by the application of a uniform radially outward force to the stent in the fully contracted state. It may serve as a clamp or collar, an expansion ring or a stent. Larger stents may be formed by interconnecting a plurality of such rings.

Similar products may also be formed from other multistable units cells.

Figs. 24a and 24b illustrate one such possibility schematically in which hexagonal unit cells such as those shown in Figs. 22a, b may be joined together to form a ring. The top member 884 of each cell 880 is joined with a the bottom portion 886 or modified 'U' shaped bottom member 890. Although shown in strip form in Figs. 24a and 24b, end 894 can be joined to end 898 to form a ring. The strip of Fig. 24a is shown in fully expanded state in Fig. 24b. Adjacent cells 880 are seen in their expanded state. For the sake of completeness, the hinges are designated 902. Fig. 24c shows one cell 920 in the process of expanding and one already expanded cell 924. The cells 920 and 924 are joined at bottom member 928 and top member 932. Hinges are shown at 936. Multiple strips may also be joined together so as to form a stent whose length is a multiple of the length of the unit cell. In such a case, upper side members of adjacent cells would be joined together. This is illustrated in Fig. 24d which, like Fig. 24c shows cells 940 in the expanded state and cells 944 in the process of expanding. Upper side members 948 are shown by dashed lines. Adjacent strips of interconnected cells 952 are joined together by upper side members 948 as well as by oblique regions 956 of bottom members 960.

It should be noted that the inventive devices of the present application may be used on a temporary basis or on a permanent basis in the body. Thus, for example, permanent stents and clamps are contemplated, as are removable stents and clamps.

It should further be noted that in expanding some of the inventive multistable cells, there may be components of expansion/contraction in a direction perpendicular to the direction of the force applied to expand the cells.

Finally, for the purposes of this application, the term 'multistable' is intended to include 'bistable'.

In the described drawings and text only some examples of different embodiments have been given. While the stents of the present invention can appear similar to prior stents, the mechanical results are completely different due to the special combination of a rigid section and a more flexible section in the same unit cell. Of course there are, beside the illustrated sinusoidal shape many other possible basic shapes for the unit cells, with similar characteristic behavior.

From the above disclosure of the general principles of the present

invention and the preceding detailed description, those skilled in this art will readily

comprehend the various modifications to which the present invention is susceptible. It is intended for the coverage of the present application to include different geometries, different constructions and different combinations of one or more materials to obtain the same basic mechanical behavior as exhibited by the above described examples.

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What is claimed is:

1. A medical device containing at least one unit cell, existing from at least two different segments, one segment being relatively flexible and the other segment being relatively rigid, mechanically connected in such a way, that the more rigid segment hinders the deformation of the more flexible segment in one main direction, resulting in a structure that can be deformed into the other main direction, about perpendicular to the first main direction, between a first more or less stable collapsed shape and a second more or less stable expanded shape.

2. A unit cell as claimed in claim 1, having a symmetrical load-displacement characteristic around the equilibrium center position.

3. A unit cell as claimed in claim 1, having an asymmetrical load-displacement characteristic around the equilibrium position, with the expanded shape being the most stable one.

4. A unit cell as claimed in claim 1, having an asymmetrical load-displacement characteristic around the equilibrium position, with the collapsed shape being the most stable one.

5. A unit cell as claimed in claims 1 to 4, where the different characteristics are mainly determined by differences in geometry of said flexible and rigid segments.

6. A unit cell as claimed in claims 3 to 5, where the different characteristics are only or also determined by differences in the unstrained shape of the segments, by prior plastic deformation and/or final heat treatment and/or by the use of difference material for the distinct segments.

7. A unit cell as claimed in claims 1, 2, 4, and 6, used as a clip to clamp or hold a body part or several body parts.

8. A unit cell as claimed in claims 1, 2, 3, 5, and 6, used as an expander to spread a body cavity open or hold several body parts apart.

9. A structure made from an arrangement of unit cells as claimed in claims 1 to 6, in such a way that seen along the most deformable direction of the unit cell, each or most of the flexible segments of the unit cells are connected to the rigid segments of the adjacent unit cell by means of joints, located at or near the point of maximum deflection of each flexible segment.

10. A stent, made from a structure as claimed in claim 9, by connecting specific segments of different unit cells, thus erecting a hollow, collapsible and expandable body, with different stable diameters, depending on the amount and location of unit cells that are in their stable expanded shape.

11. Each of the products as claimed in claims 1 to 10, at least locally made from a plastic deformable material or an elastical deformable material.

12. Each of the products as claimed in claims 1 to 11, made from a polymer, a metal, a composite, a shape memory material with superelastic behavior, a shape memory material with temperature sensitive behavior or a combination of two or more of these materials.

13. Each of the products as claimed in claims 1 to 12, where an increased flexibility within a unit cell is obtained by locally changing the geometry of the most flexible section along its length.

14. Products as claimed in claim 13, where the increased flexibility is caused by elastic hinges.

15. Products as claimed in claim 13, where the increased flexibility is caused by plastic hinges.

16. A stent as claimed in claims 10 to 15, where the flexibility between adjacent unit cells in tangential and/or axial direction is increased by separating these unit cells by plastic or elastic deformable hinges.

17. A stent as claimed in claims 10 to 16, where the flexibility between adjacent unit cells in tangential and/or axial direction is increased by separating these unit cells completely from each other.

18. A stent as claimed in claims 16 and 17, where a series of short stents with bistable unit cells are connected in axial direction by flexible joints with different geometry.

19. A stent as claimed in claims 10 to 18, where a number of bistable unit cells is combined with unit cells with a different characteristic.

20. A stent as claimed in claim 19, where the cells with different characteristic are balloon expandable, self-expanding or temperature sensitive.

21. One or more stents as claimed in claims 10 to 20, used in combination with a graft stent.

22. A stent as claimed in claim 21, where the bistable stent is used to press a graft stent against a second stent that at least partly surrounds the graft stent and the bistable stent.

23. A stent as claimed in claims 10 to 22, that is made removable by collapsing it back to its smallest stable diameter before removal.

24. A stent as claimed in claims 10 to 23, that contains not only unit cells that expand in tangential direction, but also in different directions.

25. A stent as claimed in claims 10 to 24, that does not only have a cylindrical section, but also tapered sections.

26. A stent as claimed in claims 10 to 25, where at least some unit cells have an asymetrical load-displacement/characteristic with a collapsed shape that it not stable.

27. A medical device using a unit cell as claimed in claims 1 to 9, where the triggering to move from the collapsed shape to the expanded shape or vice versa is caused by pneumatic, hydraulic, mechanical or electromechanical means.

28. A stent as claimed in claims 10 to 26, where the triggering to move from the collapsed shape to the expanded shape or vice versa is caused by pneumatic, hydraulic, mechanical or electromechanical means.

29. A medical device as claimed in claims 1 to 28, where the unit cell is made of an arrangement of relatively rigid sections, connected by plastic or elastic deformable joints.

30. A medical device having a plurality of stable configurations, the device comprised of a plurality of interconnected cells, each cell having a cell structure, the cells including a relatively rigid section and a relatively flexible section interconnected so as to define the cell structure in the form of a multistable spring system having a plurality of stable configurations.

31. The medical device of claim 30 wherein the cell structure is bistable having two stable configurations.

32. The medical device of claim 31 wherein the cells are constructed and arranged so that the device may be switched between two stable configurations by applying a uniform radially directed force.

33. The medical device of claim 31 as a tubular stent having two or more configurations including an unexpanded configuration and a fully expanded

configuration, the diameter of the stent in the fully expanded configuration exceeding the diameter of the stent in the unexpanded configuration.

34. The medical device of claim 30 wherein the cells are designed and arranged to provide a range of diameters in step-wise fashion.

35. The medical device of claim 34 as a tubular stent having an initial diameter at a first end, a final diameter at a second end and at least one intermediate diameter between the first and second ends, the intermediate diameter differing from the initial and final diameters.

36. The medical device of claim 35 wherein the initial and final diameters are the same.

37. A tubular stent having a surface, the stent comprising a plurality of cells having a plurality of stable states, the cells on the surface of the stent, the cells having at least a first stable state and a second stable state, the cells in the second state encompassing a larger area than the cell in the first state, the cells characterized by a negative spring constant, the cells constructed and arranged so that the stent is characterized by a plurality of stable states.

38. The stent of claim 37 wherein the cells are bistable having first and second stable shapes.

39. The stent of claim 38 wherein the cells are arranged and disposed such that the stent has at least two stable states, including a first stable state in which the stent is characterized by a first diameter and a second stable state in which the stent is characterized by a second diameter, the second diameter larger than the first diameter.

40. The stent of claim 38 further having a third stable state, the third stable state having a third diameter different from the first and second diameters.

41. The stent of claim 38 wherein the cells are formed from at least two different segments:

a first segment which acts as a relatively rigid support for the cell, and

a second segment which is more pliable than the first segment, the second segment capable of existing in two distinct states, a first contracted state corresponding to the first stable state of the cell and a second expanded state corresponding to the second stable state of the cell, the first and second segments fixedly connected one to the other.

42. The stent of claim 41 wherein the cells are constructed and arranged so that the stent has two stable states, a contracted state having a first diameter and an expanded state having a second diameter larger than the first diameter.

43. The stent of claim 41 wherein the first and second segments are formed of the same material, the first segment having a first cross-sectional area and the second segment having a second cross-sectional area in excess of the first cross-sectional area.

44. The stent of claim 41 wherein the first and second segments are made of different materials, the material of the first segment being more rigid than the material of the second segment.

45. The stent of claim 41 wherein the first and second segments are made of the same material, the first segments being strengthened by heat treating so as to increase the rigidity of the first segments.

46. The stent of claim 41 having a uniform diameter and having three or more stable states, the diameter of the stent differing in each stable state.

47. The stent of claim 41 constructed and arranged to have three or more stable states, the stent having different diameters in some of the stable states, the stent comprised of a plurality of bistable cells of two or more types, the cell types requiring differing amounts of force to expand.

48. A method of implanting an expandable stent having a plurality of stable configurations comprising the steps of:

1) applying the stent to a balloon mounted on a catheter;

2) delivering the stent to a desired bodily location;

3) inflating the balloon so as to expand the stent from a first stable configuration to a desired second stable configuration, the second stable configuration exhibiting a larger diameter than the first stable configuration; and

4) deploying the expanded stent at the desired bodily location.

49. The method of claim 48 wherein the stent is applied to the balloon in the second stable configuration during the applying step and further comprising the step of:

applying radially pressure inward on the stent so as to urge the stent into the first stable configuration.

50. The method of claim 48 wherein the stent is applied to the balloon in a third

stable state during the applying step, the diameter of the stent in the third stable state intermediate between the diameter in the first state and the diameter in the second state and further comprising the step of:

applying radially pressure inward on the stent so as to urge the stent into the first stable configuration.

51. An expandable stent having an initial condition and an expanded condition, the stent having a plurality of diameters along its length in the expanded condition, the stent comprised of a plurality of cells having a plurality of stable states, the cells encompassing different areas in the different states.

52. An expandable device comprising one or more multistable loops, the loop having at least a first state and a second state, the loop encompassing a first area in the first state and a second area in the second state, wherein the device is expanded by applying a force thereto.

53. The device of claim 52 comprising a first arcuate member having first and second ends and a second arcuate member having first and second ends,

the first end of the first member in communication with the first end of the second member, and

the second end of the first member in communication with the second end of the second member,

wherein the second member is more pliable than the first, the second member capable of assuming a first stable position and a second stable position.

54. A clamp for securing a bodily member selected from the group consisting of body tissue, body organs, body lumens and body vessels comprising the device of claim 1 and further comprising a triggering means for triggering the device to alter from one state to the other.

55. A tubular graft stent comprising one or more expansion rings, each expansion ring capable of assuming first and second stable configurations,

the expansion rings formed of a first member and a second member, the second member more pliable than the first member, and having a first and a second stable position, the first stable position corresponding to the first stable configuration and the second stable position corresponding to the second stable configuration, the ring

encompassing a greater area in the second stable configuration than in the first stable configuration,

the stent having a surface, the surface comprising a skin mounted on the expansion rings.

56. The stent of claim 55 wherein the skin is selected from the group of materials consisting of polymeric materials, human skin, animal skin, human tissue and animal tissue.

57. The stent of claim 56 having two expansion rings, a first expansion ring at a first end of the stent and a second expansion ring at a second end of the stent.

58. The stent of claim 57 having a first diameter at the first end and a second diameter at the second end.

59. A stent having an unexpanded configuration and an expanded configuration,

the stent having a surface,

the stent comprising:

a plurality of generally longitudinal, wave-like first members characterized by a first wavelength, and having peaks and troughs; and

a plurality of generally longitudinal wave-like second members characterized by a second wavelength, and having peaks and troughs,

the second wavelength substantially equal to the first wavelength, the second members capable of stably assuming two positions,

a first position corresponding to the unexpanded configuration in which the first and second members are in phase and

a second position corresponding to the expanded configuration, in which the first and second members are 180° out of phase, the first members more rigid than the second members,

the first and second longitudinal members disposed on the surface of the stent, the longitudinal first and second member alternating,

each peak of each first member attached to one adjacent peak of a second member in a region of attachment,

each trough of each first member attached to one adjacent trough of a second member in a region of attachment,

the regions of attachment separated by one wavelength,

whereby the stent can be snapped from the unexpanded configuration to the expanded configuration by applying a radially outward or tangential force thereto and the stent can be snapped from the expanded to the unexpanded configuration by applying a radial inward or tangential force thereto.

60. A method of joining together two bodily vessels comprising the steps of:

delivering the stent of claim 40 in a first stable state corresponding to an unexpanded configuration to a bodily site;

expanding the stent to a second stable state, the diameter of the stent exceeding the diameter of the vessels;

placing the stent over the vessels to be joined; and

contracting the stent to a third stable state, the diameter of the stent in the third stable stent intermediate between the diameter of the stent in the first and second stable states, whereby the stent rests snugly upon the vessels.

61. The method of claim 60, the stent having a first end a second end, further comprising the steps of:

positioning one or more devices as in claim 52 in the form of an expander ring inside the vessels and underneath a portion of the stent; and

expanding the one or more devices so as to clamp the vessel between the device and the stent.

62. A method of joining together two bodily vessels comprising the steps of:

delivering the stent of claim 39 in a first stable state corresponding to an unexpanded configuration to a bodily site;

placing each of the bodily vessels over at least a portion of the stent, the diameter of the vessels exceeding the diameter of the stent in the first stable state; and ;

expanding the stent to a second stable state, the diameter of the stent in the second stable state chosen so that the vessels fit snugly over the stent.

63. The method of claim 62 further comprising the steps of:

positioning one or more collars around the vessels and over a portion of the stent so as to clamp the vessel in place in between the stent and the collar.

64. A method of joining together a first and a second vessel, the first vessel having an

end and the second vessel having an end, comprising the steps of:

placing a rigid support collar over the end of the second vessel;

placing at least a portion of the first vessel in at least a portion of the second vessel;

positioning an expansion device as in claim 52 in the form of an expansion ring interior to the first and second vessels; and

expanding the expansion ring so as to clamp the vessels together.

65. A stent as in claim 37 wherein the cells are expandable from the first to the second stable state, the expansion having a tangential component and an axial component.

66. A bistable valve for opening and closing a tubular device comprising:

1) a conduit, the conduit having an interior, an inner wall and an outer wall;

2) a stop surface extending across the interior of the conduit, the stop surface having an opening within;

3) a snap-action bipositional unit cell, the unit cell including

a flexible member, the flexible member substantially arcuate, the flexible member having a first end and a second end,

the first end in communication with a triggering means,

the triggering means supported by a support means

emanating from the inner wall of the conduit,

the second end anchored to the stop surface,

the bipositional unit cell constructed and arranged so that the flexible member may assume a first position corresponding to a closed position and a second position corresponding to an open position;

4) a valve closure member actuated between open and closed position by the flexible member, the valve closure member constructed and arranged so as to completely close the opening in the stop surface when the flexible member is in the closed position, the valve closure member further constructed and arranged so that the opening is open when the flexible member is in the opened position,

whereby the conduit may be opened by triggering the triggering means so as to allow the flexible member to move between the closed position and the opened position,

and

the conduit may be closed by triggering the triggering means so as to allow the flexible member to move between the opened state and the close state.

67. The bistable valve of claim 66 wherein the triggering means is a piezoelectric element, the piezoelectric element serving as a restraining means for restraining the flexible member, the piezoelectric element triggering the flexible member to flip by undergoing a small decrease in length upon introducing a small current thereto, thereby releasing the flexible member.

68. The bistable valve of claim 66 wherein the support means is a rigid member relative to the flexible member.

69. The bistable valve of claim 66 wherein the stop surface has two oblique regions, the oblique regions being oblique relative to the longitudinal axis of the tube, with a longitudinal region therebetween, the opening disposed in the longitudinal region.

70. A medical device for use in the human body comprising the bistable valve of claim 66.

71. A medical device for use in controlling urinary incontinence, the device comprising the bistable valve of claim 66.

72. A method of controlling urinary incontinence comprising the steps of:

1) inserting a medical device as in claim 71 into a portion of a urethra; and

2) optionally clamping the medical device in place by applying a clamp as described in claim 54 to the outside of the urethra;

wherein urine may be voided by triggering the valve so as to switch it from the closed to the opened position, the valve being triggered so as to close following urination.

73. A medical device including at least one multistable unit cell, the multistable unit cell formed from at least four relatively rigid segments, each relatively rigid segment having a first end and a second end, each first end connected to a second end of an adjacent segment by a plastically or elastically deformable hinge and each second end connected to a first end by a plastically or elastically deformable hinge so as to formed a closed cell, whereby the multistable unit cell can be switched between a first stable fully collapsed shape and a second stable fully expanded shape.

74. A medical device as in claim 73 in the form of a stent comprising a plurality of multistable units cells having four relatively rigid segments, the stent having at least two stable configurations including a first fully collapsed configuration having a first area and a second fully expanded configuration having a second area larger than the first area.

75. A medical device as in claim 74 in the form of a stent wherein the multistable unit cell has:

a top segment;

a bottom segment, the bottom segment including a portion that is substantially parallel to the top segment, the parallel segment having first and second ends, and two oblique portions that are disposed at oblique angles relative to the parallel portion, each oblique portion situated at an end of the parallel portion;

a first segment connecting the bottom and top segments

and a second segment connecting the bottom and top segments, the first and second segments of substantially equal length, the cell symmetric about an axis that bisects the top and bottom segments.

76. A medical device as in claim 75 in the form of a stent wherein the multistable unit cell assumes a hexagonal shape in its expanded state.

77. A medical device as in claim 74 in the form of a stent wherein the multistable unit cell has:

a curved top segment;

a bottom segment, the bottom segment substantially parallel to the top segment,

a first segment connecting the bottom and top segments

and a second segment connecting the bottom and top segments, the first and second segments of substantially equal length, the cell symmetric about an axis that bisects the top and bottom segments.

Fig. 1a

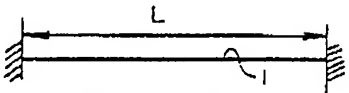


Fig. 1b

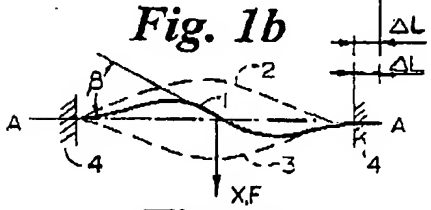


Fig. 1c

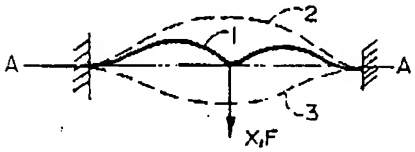


Fig. 2

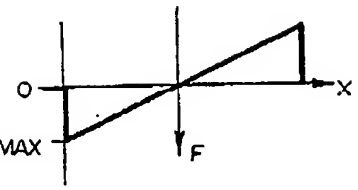


Fig. 3

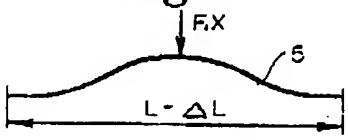


Fig. 4

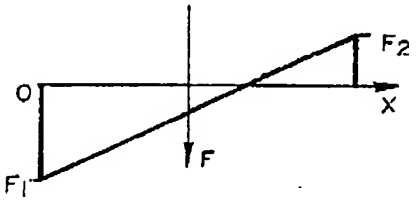


Fig. 5a

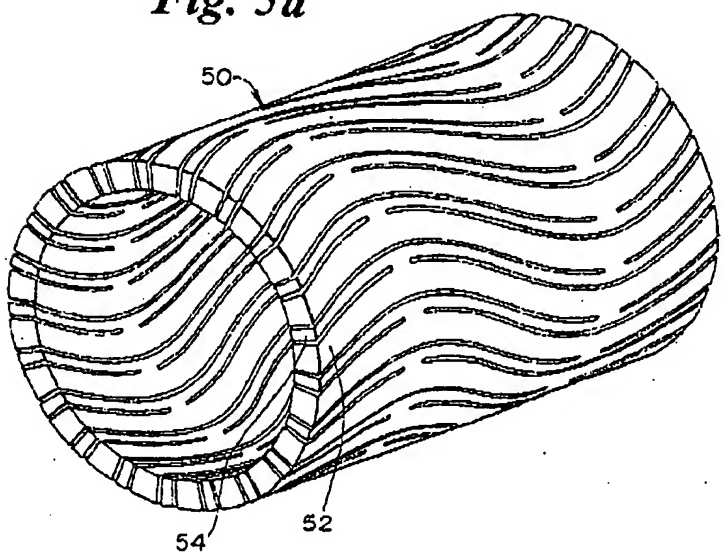


Fig. 5b

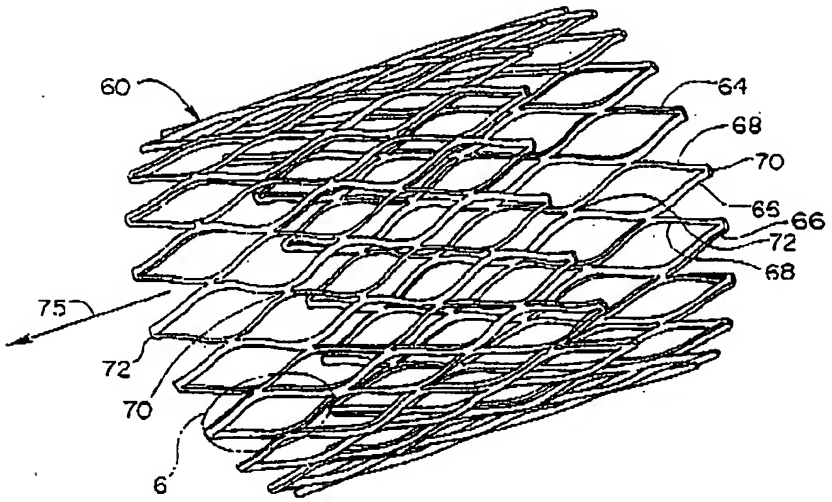


Fig. 6

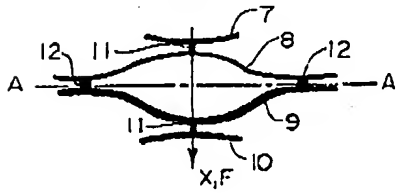


Fig. 7

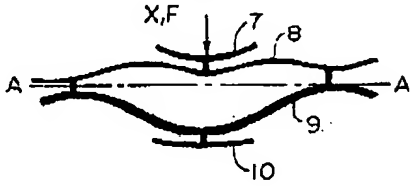


Fig. 8

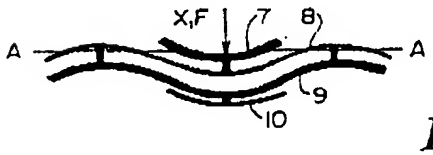


Fig. 9

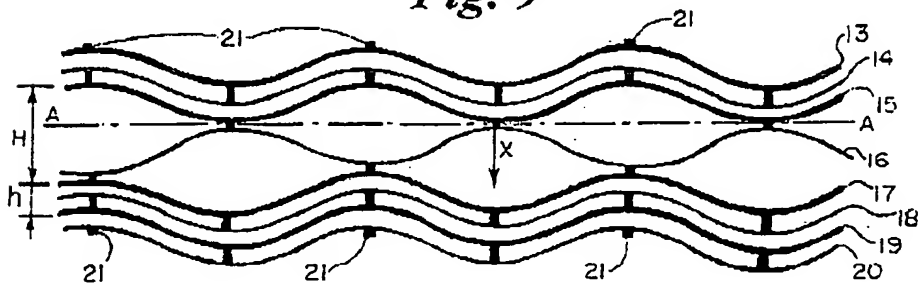


Fig. 10

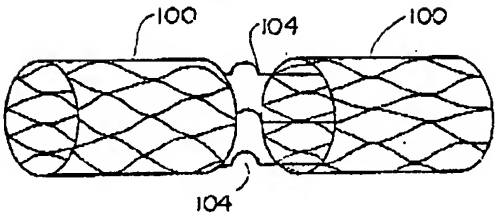


Fig. 11

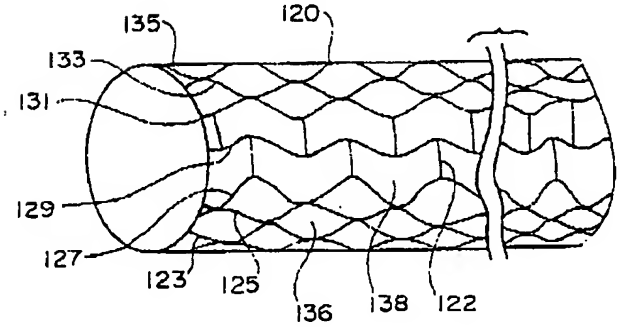


Fig. 12

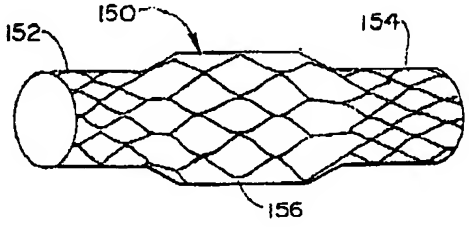


Fig. 13

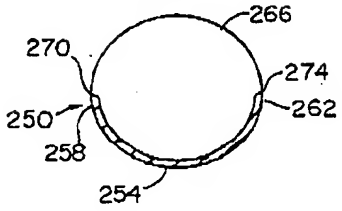


Fig. 14

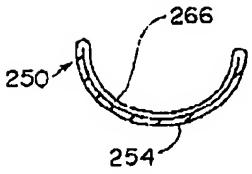


Fig. 15

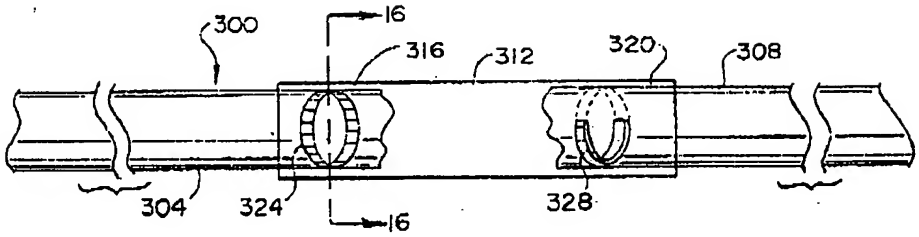


Fig. 16

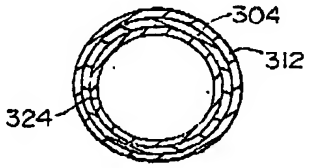


Fig. 17

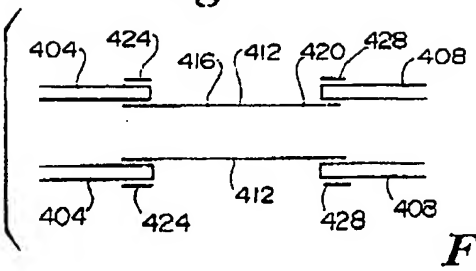


Fig. 18

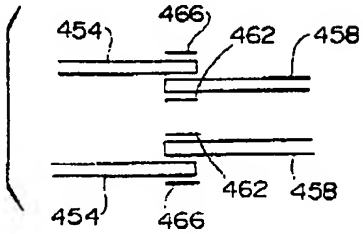


Fig. 19

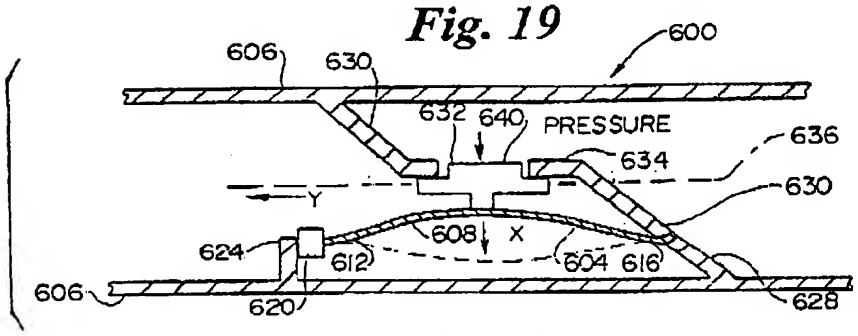


Fig. 20

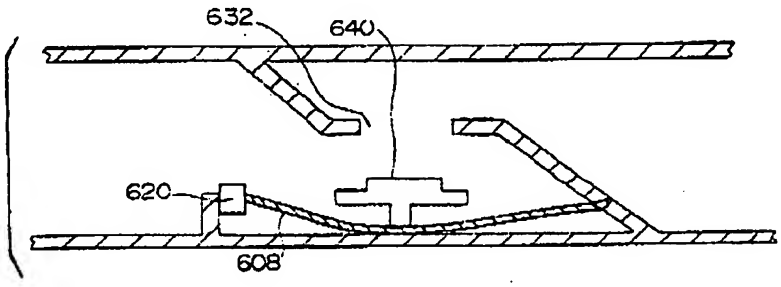


Fig. 21a

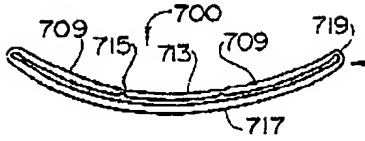


Fig. 21b

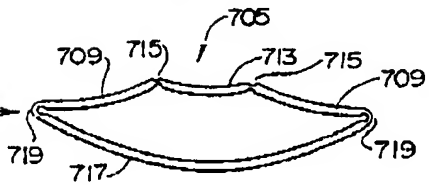


Fig. 22a

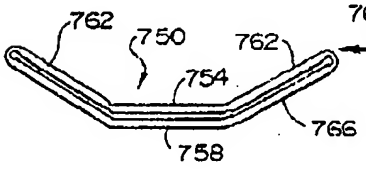


Fig. 22b

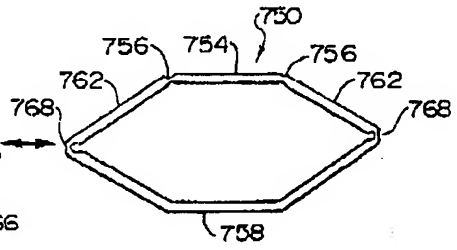


Fig. 23

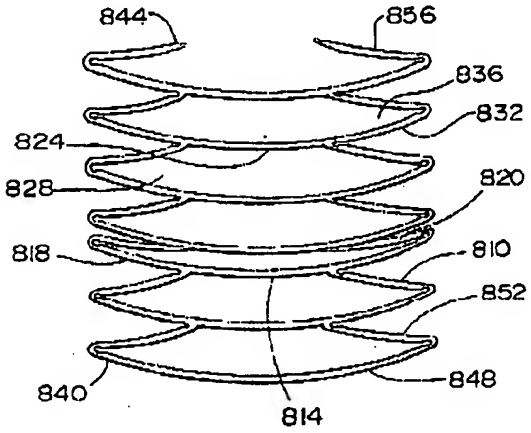


Fig. 24b

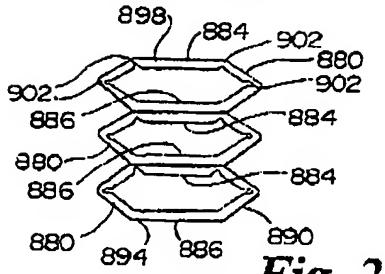


Fig. 24a

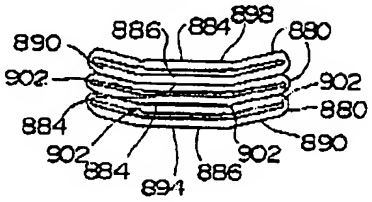


Fig. 24d

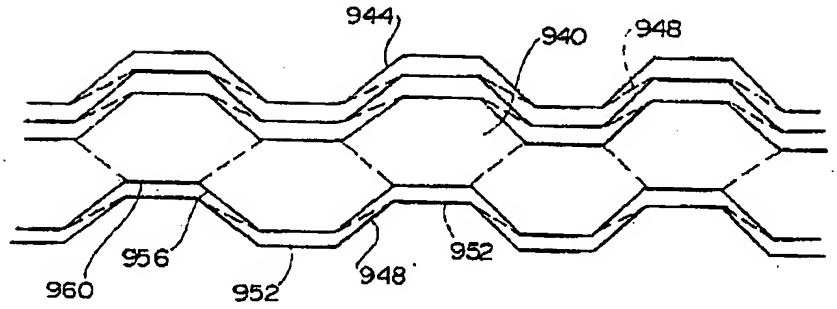
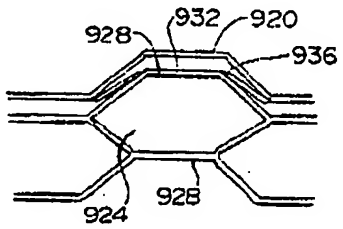


Fig. 24c



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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : **A61F 2/06, A61B 17/11, A61F 2/00, F16K 31/00**

A3

(11) International Publication Number: **WO 98/32412**

(43) International Publication Date: 30 July 1998 (30.07.98)

(21) International Application Number: PCT/US98/01310

(22) International Filing Date: 23 January 1998 (23.01.98)

(30) Priority Data:
60/036,359 24 January 1997 (24.01.97) US

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(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

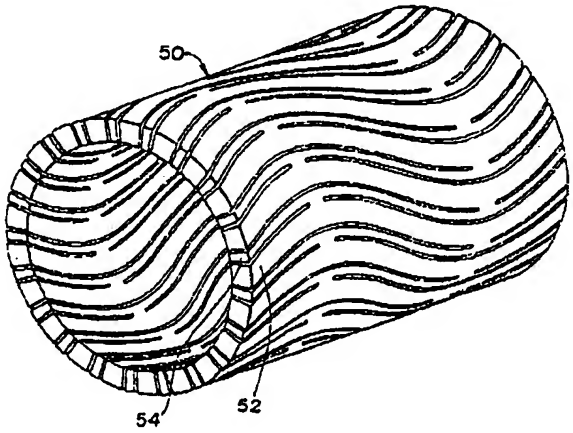
Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

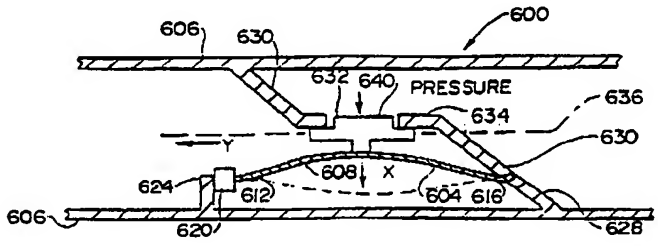
(88) Date of publication of the international search report:
12 November 1998 (12.11.98)

(54) Title: BISTABLE SPRING CONSTRUCTION FOR A STENT AND OTHER MEDICAL APPARATUS

(57) Abstract

The present invention is directed to bistable cells and their use in devices, particularly medical devices such as stents, clamps and valves. An expandable stent formed of a plurality of bistable cells is described. The stent has two or more stable configurations, including a first stable configuration with a first diameter and a second stable configuration with a second, larger diameter. A valve comprising a bistable cell for use in eliminating incontinence is also disclosed.





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INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/US 98/01310

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06 A61B17/11 A61F2/00 F16K31/00

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61B F16K F16L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category '	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 18359 A (FOUERE) 20 June 1996 see abstract; figures 1,2	1,11-13, 17-21, 28-33
X Y	WO 95 09584 A (GUERBET) 13 April 1995 see page 9, line 26 - page 10, line 12; figures	1,11-13, 21, 28-33, 55-57 58
X	WO 96 09013 A (WAKE FOREST INIVERSITY) 28 March 1996 see abstract; figures 10,14	1,11-13, 30-33

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of theinternational search	Date of mailing of the international search report
4 September 1998	16.09.98

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

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INTERNATIONAL SEARCH REPORT

Int .tional Application No
PCT/US 98/01310

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 5 562 690 A (GREEN ET AL) 8 October 1996	1,54
A	see column 5, line 36 - column 7, line 13; figures 1-8	7,8
P,X	US 5 695 516 A (FISCHELL ET AL.) 9 December 1997	1,9, 11-13, 15,16, 28-33
A	see the whole document	2-4
P,X	WO 97 04721 A (MEDSTENT) 13 February 1997	1,4, 11-13, 28-33
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Y	EP 0 587 197 A (ANGIOMED) 16 March 1994 see claim 7	58
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A		37-39, 41-43, 46,47
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Int. ational Application No
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Int ational Application No
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A		74,75
X	EP 0 421 729 A (MEDTRONIC INC) 10 April 1991 see abstract; figures	73,74
A	US 5 141 360 A (ZEMAN DAVID) 25 August 1992 see column 5, line 34 - line 68; figure 3	73-76
A	WO 95 32757 A (NITINOL MEDICAL TECHNOLOGIES I) 7 December 1995 see abstract; figures	73-76

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/01310

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 48-50 60-64 72
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 98/01310

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-36, 54-58

   A medical device containing at least one unit cell with one relatively flexible segment and one relatively rigid segment

   1.1 Claims 1,2,5-29

   A unit cell with symmetrical load-displacement

   1.2 Claims 1,3,5-29

   A unit cell with asymmetrical load-displacement characteristic, most stable in expanded state

   1.3 Claims 1,4-29

   A unit cell with asymmetrical load-displacement characteristic, most stable in collapsed state

   1.4 Claims 30-36

   A medical device with a multistable spring system

   1.5 Claim 1,54

   A clamp

   1.6 Claims 55-58

   A graft stent with expansion rings

2. Claims: 37-47,65

   A stent with a negativ spring constant

3. Claim : 51

   A stent with a plurality of diameters

4. Claims: 52, 53

   An expandable device

5. Claim : 59

   A stent with wavelike members

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

6. Claims: 66-71

A bistable valve

7. Claims: 73-77

A medical device with a cell with four rigid segments

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int .tional Application No
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